SENSPEC
SPECTRAL MONITORING SYSTEMS

V-SPEC™

» Monitoring System

Instruction Manual

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The V-Spec™ Monitoring System is user friendly and applies ease of use fundamentals. Please read this operating manual carefully before starting the system to familiarize yourself with the operation of the VSMS. All warnings and safety instructions are listed here.

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Declaration of Guarantee

The manufacturer warrants the original purchaser of this product that each new component of the V-Spec™ Monitoring System (see list of components) is free from defects in workmanship and materials. Under the warranty, the manufacturer is only obliged to replace one component which is, covered by the guarantee. at the sole discretion of the manufacturer.

Warranty exclusion and performance of the system

The Senspec GmbH can neither warrant nor verify the performance parameters of the device and expressly denies any warranty or liability claims in case of misuse, negligence and damaging of Senspec products or their external damaging or if the products were not used in accordance with the enclosed user guide or accessories were used which were not recommended by Senspec GmbH or repairs were performed by service personnel not authorized by Senspec.

Caution: For the United States only: Federal law restricts this device to sale on prescription and based on FDA approval.

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The V-Spec™ Monitoring System is a medical device in accordance with EU guideline 93/42/EEG and complies with international standards:

IEC 60601-1, DIN EN 80601-2-61 and EN ISO 10993-1.*

*further relevant standards which were taken into account in the product manufacture can be inquired at Senspec GmbH.

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1 RANGE OF APPLICATION AND LIMITATIONS

1.1 Range of application of the V-Spec™ Monitoring System (VSMS)

- The V-Spec™ Monitoring System (VSMS) – consisting of the V-Spec™ Monitor (VSM), the V-Spec™ Sensors and accessories is intended for the continuous and non-invasive patient monitoring.
- The basis for the V-Spec™ Monitoring System (VSMS) is the powerful, clinically proven V-Spec™ Technology which is intended for use in adults and children over 20 kg body weight in accordance with the information contained in the sensor package insert.
- The V-Spec™ Soft Sensor (REF VS-SS-L) and the V-Spec™ Sensor (REF VSS) are intended for use with the V-spec ™ Monitor if a continuous and non-invasive monitoring of vital parameters is necessary.
- The monitoring parameters are oxygen saturation (arterial) (S_PO_2), pulse (PR), tissue oxygen saturation ($S_{ti}O_2$), pulsation index (PI) and Pleth index (PLI).
- The VSMS is intended for use in hospitals, hospital-type facilities, transport within the hospital.
- The VSMS may be operated by doctors, nurses and trained nursing staff.
- The VSMS is only to be used on a medical prescription.

Caution: The VSMS measures the functional oxygen saturation.

Note: The use in the hospital includes operating theaters, specialist departments, emergency and intensive care units and wards.
Hospital-type facilities include surgery centers, special care facilities and special sleep facilities outside a hospital. Internal transportation means patient transport within

the hospital or the hospital-type institution.

Note: In the course of x-ray examinations or CT the sensor can remain on the patient but is then visible on the images. The sensor should be removed with the MRI.

1.2 Limits of the pulse-resolved spectroscopic measurement of vital parameters

The VSMS measures the vital parameters of arterial blood and the tissue. The following clinical situations or factors may affect the readings:

- Poor blood circulation, e.g. as a result of low cardiac index, shock, hypothermia or proactively blood pressure titration Drugs.
- Quality of the skin and subcutaneous tissue (e.g. direct placement over veins, damaged skin, edema, moles or a very strong subcutaneous fat layer).
- Poor contact between the sensor and the skin, where the light passes through the point of input of light and the point of output of light and thereof light can pass light directly from the light source to the spectrometer unit.
- Intra vascular dyes. Not all dyes are included in the analysis and can thus affect the chemo metric blood and tissue analysis.
- Low perfusion at the measuring point, e.g. by mechanical pressure or local hypothermia of the measuring point or part of the vascular system, which supplies the measuring point ("cold fingers")
- Skin pigmentation or tattoos. The usual skin pigmentation by Melanin is taken into account in the evaluation, since the spectral analysis is carried out on the 2nd derivation.
- Severe anemia.

- Strong ambient light.
- Arterial-venous shunts.

Warning: For the measurements the tissue is heated in the measurement volume, which sometimes may result into an increase in the perfusion and a related increase in the tissue oxygen saturation. Wait with a therapy or a diagnostic evaluation of the parameters until this physiological stabilization phase is completed.

Note: The VSMS is not a blood gas analyzer. The above-mentioned restrictions must be included in the interpretation of the values.

Note: If you compare the readings displayed on the VSM with values of arterial or venous blood gas analysis (BGA), pay attention to the following points:

- Carefully take and handle blood samples.
- Blood collection should be done in the "steady state".
- Measurement values which are determined from the BGA must be compared with the values of the VSM at the time of the blood sample.
- Make sure that the blood gas analyzer operates correctly.

Note: Techniques for the measurement of arterial oxygen saturation - including pulse oximetry - cannot determine hyperoxemia. Here tissue values can allow conditional inferences.

Note: Because of the S-shape of the oxygen dissociation curve (ODC), pulse oximetry abnormalities of breathing in patients can not be reliably detected under oxygen administration.

2 ABBREVIATIONS

LED	light-emitting diode
O_2	oxygen
PI	pulsation index
PLI	Pleth Index
POST	Power-On Self-Test
RO	responsible organization
PR	pulse rate
SaO_2	arterial oxygen saturation
VSM	V-Spec™ Monitor
VSMS	V-Spec™ Monitoring System
AT-VS	Attachment Tape
VS-EC	V-Spec™ extension cable
S_PO_2	functional oxygen saturation of arterial hemoglobin measured with a pulse oximeter
$S_{ti}O_2$	tissue oxygen saturation, oxygen saturation of the measured hemoglobin of the tissue
Hb	hemoglobin
HbO2	oxygen hemoglobin
HHb	hydrogen hemoglobin
H_2O	water
ctHb	hemoglobin concentration
HCT	hematocrit

3 WARNINGS AND PRECAUTIONS

Special warnings

Please read this owner's manual carefully and follow all instructions, warnings and precautions! The VSM must be carried out by health care professionals and be operated without prior training by Senspec. Conditions for the proper use of the VSMS are general knowledge of pulse oximetry, spectroscopic blood gas analysis and an understanding of the characteristics and functions of the device.

Risk of electric shock:

- Do not attempt to open the unit and possibly perform the maintenance yourself. If repairs or modifications to the device are performed by persons not authorized by Senspec, the warranty will be voided.
- The battery cannot be exchanged by the user
- Do not immerse the V-Spec™Monitoring System in liquids - Electric shock hazard!
- Only connect equipment intended for the system and described in chapter 9.2.3 Connections . Follow all warnings and operating instructions enclosed with your system! The V-Spec™ Monitoring system only works with the V-Spec™ Sensors or V-Spec™ Soft Sensors delivered by Senspec. Do not connect sensors of other manufacturers, the device could be destroyed. If the device is damaged due to connection of devices or sensors not intended for the use the warranty will be voided.

Risk of explosion::

The V-Spec™ Monitoring System must not be operated in the presence of flammable anesthetics or other highly flammable substances.

Risk of cross-contamination:

Clean the sensor carefully before each use, as described in the User Guide for the sensor. Only manual cleaning / disinfection procedures are permitted. For this purpose, use running water or an aldehyde-free disinfectant. If the V-Spec™ Sensor is used in conjunction with the attachment tape (Ref: AT-VS) it should be noted that the AT-VS is for one-time use only and must not be reused.

The V-Spec™ Monitoring System (not even parts of it) should not be cleaned in an ultrasonic bath, autoclaved, gas sterilized or steam sterilized.

Risk to the patient:

The V-Spec™ Sensor and V-Spec™ Soft Sensor are intended for external use only. Please note the enclosed instruction for each sensor and never use the sensors for internal applications!

- Make sure that all connections are tight and free from grease and moisture. The ingress of moisture can lead to incorrect or inaccurate readings.
- Be careful when attaching and removing the V-Spec™ Sensor with the Attachment Tape (AT-VS). The AT-VS may be used only on intact and fully developed skin.

4 SAFETY INFORMATION

4.1 Warnings

This icon indicates a **warning**. Warnings alert you to conditions that can lead to risks or injuries to the patient or a user.

Warning: The V-Spec™ Monitoring System (VSMS) may only be operated by qualified personnel. This manual, accessories instructions for use, all precautions information and specifications should be read before use.

Warning: The V-Spec™ Monitor (VSM) is not intended for the diagnosis. It is intended only as a supplement to the assessment of the patient's status. The VSMS is a non-invasive pulsatile spectrometer and no blood gas analyzer.

Warning: Lay and secure the cables carefully so that the patient can not get caught in it.

Warning: In order to ensure the safety of the patient, place the monitor so that it cannot fall on the patient and the patient cannot be hurt!

Warning: Do not move the monitor by pulling or lifting by the sensor cable or power cable. The cable connections can become loose and the device can fall on the patient and harm him.

Warning: Do not spray or pour liquids on the VSM, accessories, connectors, switches or openings in/on the housing.

Warning: If the VSM accidentally becomes wet, it must be dried before use and inspected by a qualified service employee.

Warning: Keep the VSMS (like all the other accessories) out of the reach of children. Risk of ingestion or risk of injury!

Warning: Risks of explosion and flammability. Do not use the VSMS in the presence of flammable anesthetic agents / gases or other flammable substances or in environments with increased oxygen content.

Warning: The VSM is protected against electrostatic / defibrillator discharge. However, it is possible that the parameter display fails temporarily during the discharge / defibrillation, and the values are unreliable of up to 20 seconds after defibrillation. Follow the instructions in the user's manual of the defibrillator!

Warning: During electro-surgery, the VSM, sensor and lines have to be physically separate from the electrosurgical devices. The sensor must not be placed between the cutting electrode and the counter electrode. The measured values can be influenced by the electro-surgery and can be unreliable up to 20 seconds after the end of the electro surgery.

Warning: For the protection of patients, operators, and the devices only original cables, sensors, connectors and connections distributed by Senspec may be used!

Warning: The impact on patient safety and the performance of the VSM during a diagnostic procedure of a magnetic resonance imaging (for example, CT, MRI) are not known. Remove therefore during such procedures, the sensors and cables that are connected with the VSM, from the patient!

Warning: During normal operation (except transport) it is recommended that the monitor is always connected to the electrical outlet. The VSM must be connected to a grounded (3-wire) electrical outlet. Make sure that the lines of the power and ground wires are properly connected.

Warning: For the United States, or Japan: A reliable grounding can only be achieved if the VSM is connected to an equivalent receptacle, marked with HG (hospital grade) or HGJ (Hospital Grade Japan).

Warning: This equipment has been tested and found to comply with the requirements for medical devices in accordance with the requirements of IEC 60601-1, ISO 80601-2-61 and the Council Directive 93/42/EEC. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation.

Warning: Certain types of mobile telecommunications equipment could interfere with the operation of the VSM. Therefore, mobile devices should not be used within five meters (16.4 feet) of the VSM.

4.2 Caution

This symbol indicates a **caution** statement. Warning statements relate to conditions that lead to damage or malfunction of the device.

Caution: Neither immerse the VSM nor the connections or accessories in liquid solutions.

Caution: The parts of the VSM must not be sterilized by irradiation, steam, ethylene oxide and H_2O_2 plasma. Follow the instructions for cleaning in the corresponding manuals.

Caution: If the VSM with not fully charged battery is connected to an AC power source which is interrupted or not delivering power, the monitor will not function or shut down after a short period of time. Always pay attention to the state of charge of the battery!

Caution: Make sure that the VSM is properly grounded, if the device is operating on AC power. If you are unsure whether the outlet is properly grounded, disconnect the VSM from the electrical outlet and use the VSMS in battery mode. Contact a qualified electrician to have the outlet examined.

4.3 Note

This symbol indicates **notes**, which you should consider in the use of the VSMS, in order to ensure a smooth operation. The failure to comply with the instructions does, however, not lead to adverse effects on the patient, the operator, or the VSMS.

5 VSM SYMBOLS

The following symbols are printed on the back of the VSM:

Symbol	Name	Description
	Consult instructions for use	Please pay attention to the accompanying documents!
	Catalog number	Indicates the catalog description.
	Serial Number	Indicates the serial number of the device.
	Date of manufacture	Specifies the year of manufacture.
	Potential balance	Connection for potential balance (ground)
	Type BF defibrillator protected	Degree of protection against electric shock: Type BF – DEFIBRILLATION, applied part
	Fuse	Indicates the fuse type.
IPX1	Degree of protection against ingress of water; type IPX1	Degree of protection against ingress of water; type IPX1: Splash-proof
CE 0482	CE-marking	CE declaration for the device
	Caution	Security related information is included in the enclosed documents.
	WEEE old device disposal	The consumer must dispose waste equipment (Waste Electrical and Electronic Equipment WEEE)according to the European waste legislation following the WEEE Statement: Do not dispose with household waste! Use the appropriate collection points!

6 THE V-SPEC™ MONITORING SYSTEM (VSMS)

6.1 Components and delivery

The V-Spec™ Monitoring System (VSMS) contains the following main components:

- V-Spec™ Monitor (VSM) including power cord with a country-specific connection

- V-Spec™ Sensor
  - V-Spec™ Soft Sensor (VS-SS-L) and / or

  - V-Spec™ Sensor (VSS)

- V-Spec™ extension cable (VS-EC)

- V-Spec™ Sensor Attachment Tape (AT-VS)

- VSMS manual (country specific)
- VSMS Manuals on CD (with full information, , VSM technical manual in English only, instructions for the use of V-Spec™ Sensors and Accessories etc.)

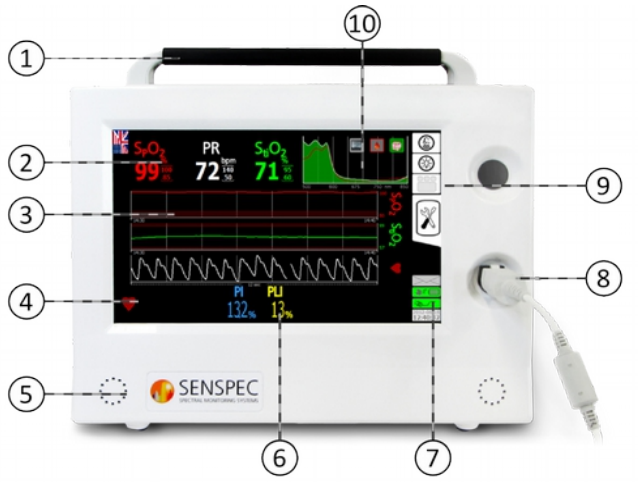
Verify the products for completeness and any external damage. If you should detect damage or defects despite careful processing and packaging by Senspec, do not plug in the appliance and contact the customer care of Senspec. We provide an easy and quick replacement or repair.

Further instructions on operating the V-Spec™ Sensors are available in the respective operating instructions. In order to ensure an error-free operation of the VSM, please follow the instructions in this manual.

Note: The components listed above are not necessarily also included in the delivery. A complete list of all available articles including accessories and supplies can be found on the Senspec website www.senspec.com.

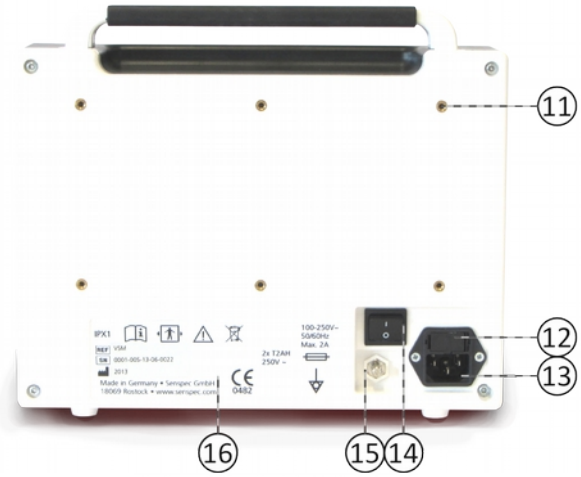
Note: In the following, only the V-Spec™ Sensor will be addressed. Thereby it is expressly referred to all models of the V-Spec™ Sensor.

6.2 Description of the monitor



<u>Front view:</u>

1 handle
2 display area medical parameters
3 display area trend graph
4 heart symbol
5 speaker
6 display area technical parameters
7 display area status indicators / change of language
8 sensor socket
9 display area settings
10 display area spectra



<u>Rear view:</u>

11 VESA mount mounting sockets
12 fuse box
13 power connector
14 power switch
15 ground connection
16 type plate

<u>Right side view:</u>

17 RS232 connector (male)

6.3 Setting up the V-Spec™ Monitor (VSM)

6.3.1 Connection to the AC power

Connect the monitor to the power source, by inserting the appliance plug of the power cord into the socket (13) on the rear of the unit and the mains plug of the power cord into a properly grounded power source. Use only power outlets that meet the requirements for hospitals. The V-Spec™ system requires 100-240VAC / 50 or 60Hz..

The charging of the internal battery is done with the power supply. A fully charged battery allows an operating duration of approximately one hour. When the device is switched on the battery indicator informs you about the battery charge level. Full charging of a discharged battery can take up to 4 hours.

Caution: Charge the battery fully before initial start-up!

The connection for a ground (earth pin) (15) offers if needed a redundant connection to the external ground conductor.

6.3.2 Turning the VSM On and Off

The power switch (14) turns the monitor on and off. When you turn on the VSM, first of all, the fan can be heard. After about 30 seconds the VSM is ready for operation.

Turning off the VSM is carried out in any case by flipping the power switch (14) to the „0"-position. If the system was shut down after a "Critical battery" alarm the power cord must be connected to power up the system. A repeated flipping of the power button is not necessary. The settings made by the user remain partially intact as explained in chapter 7.3 Alarm-System-Reset in more detail.

6.4 Connection of a V-Spec™ Sensor

Connect the sensor plug to the socket (8) on the VSM. Make sure that the flat side of the plug securing points upwards and the connector clicks into place. Check the sensor status with the help of the sensor status indicator on the screen of the powered-on VSM (7.4). To remove the sensor, push the plug securing and gently pull the connector from the device.

Caution: Use only genuine V-Spec™ Sensors! By connecting other (i.e. third party) sensors the connection and the system can be damaged. Senspec guarantees a proper function of the system only if genuine equipment is connected. The V-Spec™ Monitoring System is only tested with V-Spec™ Sensors.

Caution: Make sure not to twist the connector plug while connecting. The plug must be plugged in or removed straight and not with excessive force.

Caution: Damaged, defective or modified sensors must not be used. Make sure that the sensor cables are undamaged. If the cables show damage, they must not be used. In this case contact your Senspec dealer or service personnel authorized by Senspec.

Caution: Do not immerse sensor and the sensor cable into water, detergents or solvents. Sensors must not be cleaned by irradiation, autoclave, or sterilization. Please note the cleaning instructions in the manual for sensors and follow them.

Prior to first use and with each patient the V-Spec™ Sensor should be cleaned as described in the User manual for the sensor. Only manual cleaning / disinfection procedures are permitted. If you are using the V-Spec™ Sensor with the Attachment Tape (AT-VS) it should be noted that the attachment tape is intended for single use and a new tape must be used for each new placement of the sensor. The V-Spec™ Sensor and the V-Spec™ Soft Sensor are suitable for repeated use.

Note: Die operating life of the V-Spec™ sensors is limited. Please refer to the instruction manual of the sensor for more information!

6.4.1 Operating the V-Spec™ Sensor with the V-Spec™ extension cable

If an extension of the sensor cable is necessary, the original V-Spec™ Extension Cable can be coupled between the sensor and the monitor. The connection of the connector of the V-Spec™ Extension Cables (VS-EC) is done in the same way as of the V-Spec™ Sensor.

Caution: Use only genuine V-Spec™ Extension Cable! By connecting other (i.e. third party) cable extensions the connection and the system can be damaged. Senspec guarantees a proper function of the system only if genuine equipment is connected. The V-Spec™ Monitoring System is only tested with V-Spec™ Extension Cable as cable extension!

6.4.2 Application of the V-Spec™ Sensor to the measuring point of the patient

Before you start with the monitoring on the patient, it's important that you become familiar with the operation of the VSM. Check the sensor status with the help of the sensor status indicator on the screen of the powered-on VSM (7.4).

The following instructions must be strictly consider when using all V-Spec™ Sensors. A correct measurement can only be carried out if all instructions are followed.

Warning: The operation of the V-Spec™ Sensors is only approved for adults and children with more than 20kg of body weight.

Warning: Do not leave the sensor longer than 72 hours at the measuring point. Is a longer monitoring necessary, change the Attachment Tape and, where appropriate, the application site. In the case of non-compliance it can lead to redness of the skin or skin inflammation. Should the skin show redness or inflammation, remove the attachment tape, and if necessary, select a new application site.

Warning: Make sure the sensor is not covered. The sensor could heat up and cause burns.

Warning: Make sure that the sensor cable is not wrapped around the patient's neck or comes to a rest there, to avoid the potential risk of asphyxiation and choking.

Warning: Avoid pressure sores! Do not apply external pressure on the sensor due to too tight band-aids, too tight bandage or a too tight headband. The measurement results could be distorted. Secure the sensor cable with the help of a strain relief in order to avoid that the optimal sensor seating is affected.

Caution: At the same time as the V-Spec™ Sensor EEG and devices to monitor consciousness can be used. Attention should be paid that the optical unit of the sensor is not affected.

Maintenance of the sensors: Please note the relevant care instructions in the owner's manual of the respective sensor. Only manual cleaning / disinfection procedures are permitted. For this purpose, use running water or an aldehyde-free disinfectant. If you are using the V-Spec™ Sensor with the Attachment Tape (AT-VS) it should be noted that the attachment tape is intended for single use and a new tape must be used for each new placement of the sensor. The V-Spec™ Sensor and the V-Spec™ Soft Sensor are not suitable for repeated use. For more information, please see the user manuals for the sensor and for the Attachment Tape.

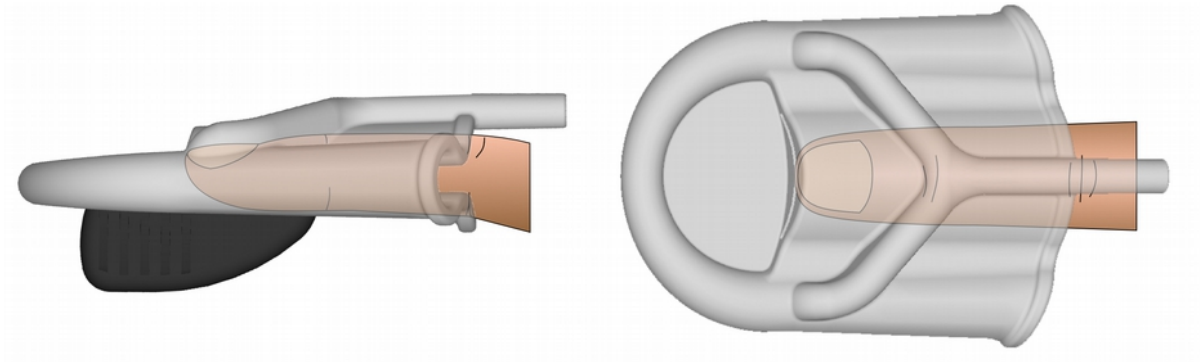
6.4.2.1 V-Spec™ Soft Sensor (VS-SS-L)

Select an appropriate measuring point for the V-Spec™ Soft Sensor Large (VS-SS-L). The index finger is ideal. Alternatively, the thumb and the other fingers are suitable as a measuring point.

Clean the application site (the finger) with a tested and approved disinfectant and dry it thoroughly. Make sure that the patient's skin is completely intact, dry and free from grease!

Apply the V-Spec™ Soft Sensor as described in the owner's manual of the sensor! Run the sensor wires to the fingers and along the arm and fix it if necessary with a plaster strip.

The following figures show a correctly applied V-Spec™ Soft Sensor:



6.4.2.2 V-Spec™ Sensor with Attachment Tape

The V-Spec™ Sensor (VSS) (in conjunction with the Attachment Tape AT-VS) should only be used on fully developed and intact skin and be used on the forehead.

Clean the application site (the forehead) with a tested and approved disinfectant and dry this location thoroughly. Make sure that the patient's skin is completely intact, dry and free from grease!

Note: Should the skin at the measuring point be not completely intact, alternatively, use the V-Spec™ Soft Sensor for the measurements.

Apply the V-Spec™ Sensor as described in the owner's manual of the sensor and the Attachment Tape. Run the sensor wires along the forehead to the outside and fix it if necessary with a plaster strip. Make sure that the cable does not pull on the sensor.

Note: Check the fit of the sensor and the quality of the measurement with the technical parameters displayed on the VSM "Pulsation Index PI". A low PI-value can point to a sensor not correctly applied.

The following figure shows a correctly fitted V-Spec™ Sensor with Attachment Tape.

Warning: The Attachment Tape is for one-time use and must be replaced after each use. Use a new tape for each measurement and each patient! Re-use can lead to cross-contamination, poor application and thus result in inaccurate readings. Use the Attachment Tape only on intact and fully developed skin.

Warning: Use only original accessories for the V-Spec™ system. Secure the sensor only with the corresponding AT-VS of Senspec. The use of other than the recommended fasteners can result in inaccurate readings.

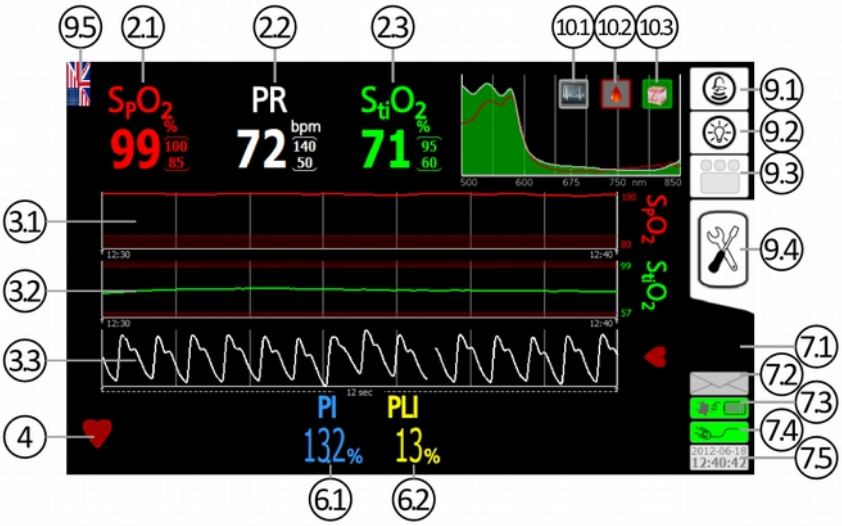
Warning: Make sure that the attachment Tape is well secured to the sensor and is completely applied on the application site of the patient! Change the AT-VS, if it is not fitting tight! The failure to do so could result in inaccurate readings.

Warning: Remove the sensor and the Attachment Tape carefully and gently! If it is difficult to remove please follow the hospital's policy on the conservation of the integrity of the skin! Where required, use commercially available non-irritating solvent for adhesive tape!

Note: In dark-skinned patients, it is possible that the skin is not detected and the sensor is displayed as not applied. In this case use the V-Spec™ Soft Sensor for measurements.

Note: It can happen that the sensor detects skin and the sensor appears as applied even though the sensor was not applied (e.g. if sensor lies on clothes). Always apply the sensor first on the patient before you connect it to the VSM!

6.5 Operating the V-Spec™ Monitors



(2) Display area medical parameter:

- 2.1 S_PO_2-value
- 2.2 PR-value
- 2.3 $S_{ti}O_2$-value

(3) Display area trend graphs:

- 3.1 trend graph field 1
- 3.2 trend graph field 2
- 3.3 trend graph field 3

(4) Heart-symbol

(6) Display area technical parameter:

- 6.1 Pulsation Index
- 6.2 Pleth Index

(7) Display area status indicators:

- 7.1 Alarm indicator field
- 7.2 Message system
- 7.3 Power-status
- 7.4 Sensor-status
- 7.5 Date and time

(9) Display area settings:

- 9.1 Alarm pause button
- 9.2 Screen brightness button
- 9.3 Spectral view button
- 9.4 Main menu
- 9.5 Language setting

(10) Display area spectra:

- 10.1 Pulsatile absorption spectrum
- 10.2 Extracted blood spectrum
- 10.3 Tissue spectrum

The main screen consists of several different areas. These include in the upper area the real time values of the parameters SpO_2, PR and St_iO_2 (2), the trend curves (3) in the central area, the heart symbol in the lower left corner (4), the values of the technical parameters PI and PLI (6) on the bottom of the screen, the display area with the status indicators (7) at the bottom right (on the top of the left site the language setting), the menu bar (9) on the right side and the display area of the spectra (10) on the upper right corner of the screen.

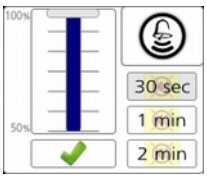
The display is equipped with a touch-sensitive touch function. By touching the screen in the appropriate place or on the corresponding icon you can open sub-menus and switch between menus.

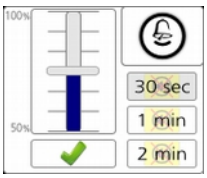
Note: The touch panel works with acoustic technology and can also be operated with gloves.

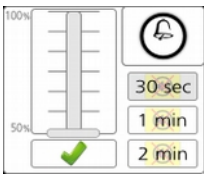
6.5.1 Setup and Settings

6.5.1.1 Pausing the alarm system

By pressing on the symbol (9.1) it is possible to temporarily pause the sound of the alarm system including the alarm system. If the button is held for longer than 3 seconds, a small menu opens, by which the pause time and the alarm volume can be adjusted. The volume of the alarms can be adjusted between 100% and 50%, whereby the button (9.1) serves simultaneously as an indicator of the current alarm volume:







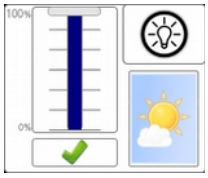
The pause time can be set to 30 seconds, one minute or two minutes. The selected time is highlighted in gray.

By simply pressing the alarm pause button (9.1) the sound output will be paused. The icon

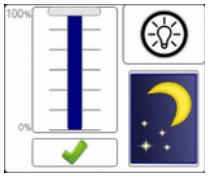
changes with paused sound output . After the expiry of the pause time the sound output is activated again and the normal symbol will be displayed.

6.5.1.2 Brightness of the screen / night mode

By touching the screen brightness button (9.2) a small window opens in which you can adjust the brightness and switch between

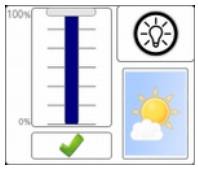
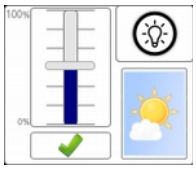
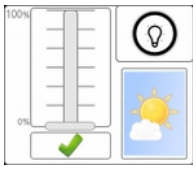
- day mode: 

and

- night mode:: 

In the night mode the screen brightness is slowly reduced ten seconds after the last user interaction, if no alarm condition exists. If an alarm occurs or the screen is touched, the brightness immediately returns to 100 %.

The screen brightness button (9.2) also serves as an indicator of the current brightness level:

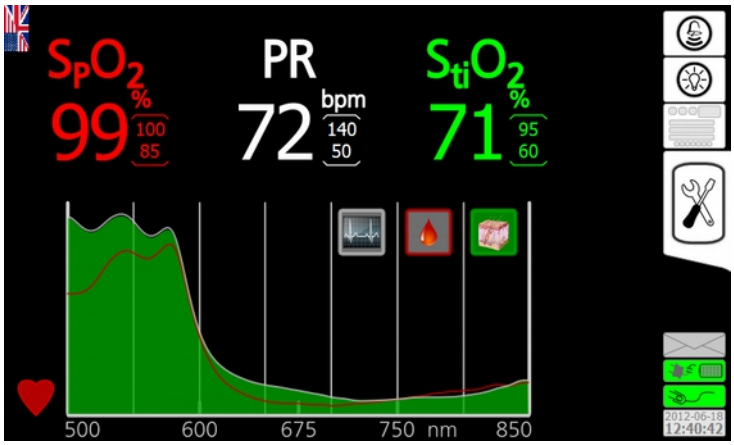
Caution: Adjust the brightness of the screen depending on the brightness of the surroundings! Important information could be missed!

6.5.1.3 Switching the screen display

The V-Spec™ Monitoring System offers you two different screens:

- the main screen described above with trend display and
- a screen with the enlarged display of the spectra (10).

With the touch of the button (9.3) a screen opens with the spectral data:



On this screen, you can see in the upper part the medical parameters and the respective alarm limits. In the lower part, a magnification of the spectra (10) is shown.

The spectral view consists of the

- **pulsatile absorption spectrum:**

  shown as white curve, the
- **extracted blood spectrum:**

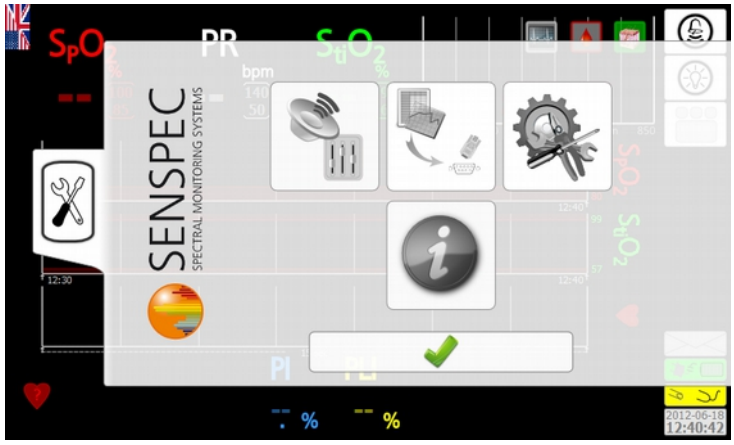
  shown as a red curve and the
- **tissue spectrum:**

  shown as a green area,

are each shown in a wavelength range of 500nm to 800nm. The button (9.3) will change in the spectra view and serves now to switch to the main screen. The display areas "Settings" (9) and "Status Indicators" (7) on the right side remain otherwise unchanged.

6.5.1.4 Main menu

By touching the menu button (9.4) the main menu opens:



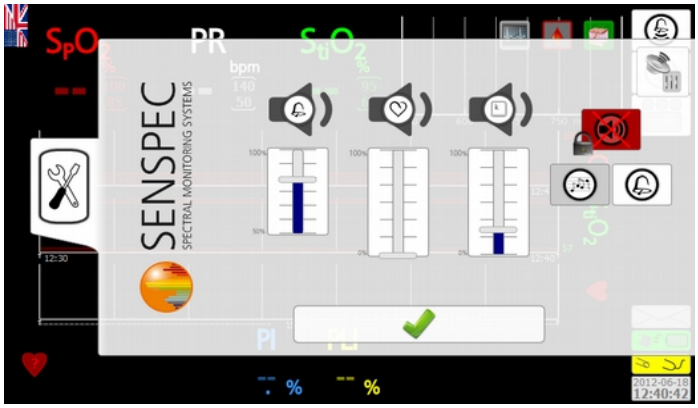
The main menu contains the following sub-menus:

- Volume menu:
- Data-output menu:
- POST and reset menu:
- Information menu:

By touching the button you can exit the menu.

Settings in the volume menu:

By touching the button the window for setting the alarm sounds opens:



With the help of the sliders you can adjust the volume for the

- alarm sounds
- the heart sound
- and the key sound

With the alarm off button authorized users can disable the audio output including the alarm system. This option is secured with a PIN-code. The user will be made aware by an audible tone at regular intervals that the acoustic alarm output is disabled. When operating the VSMS with connected systems the alarm forwarding will continue.

With the "melody button" and the "sound button" you can select if the optional alarm melodies (see section "alarms and messages") or sounds shall be used. The selected field is shown in gray.

Setting data output:

In the data-output menu you can select how the output of measurement data via the serial RS232-interface (17) shall be done.

You have the option to choose between the

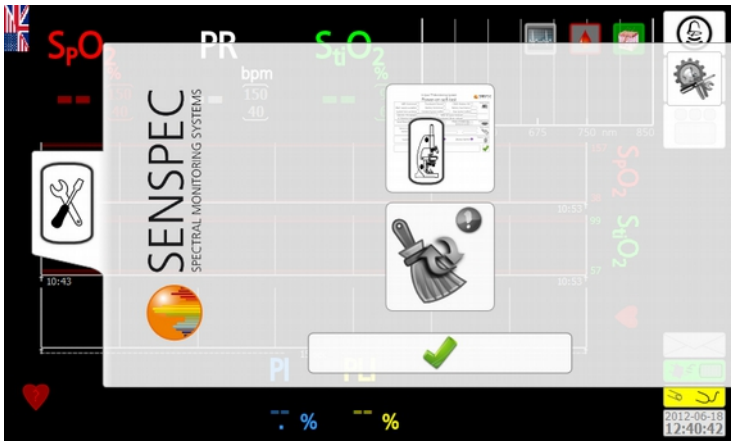
- V-Spec™ Link protocol

and the

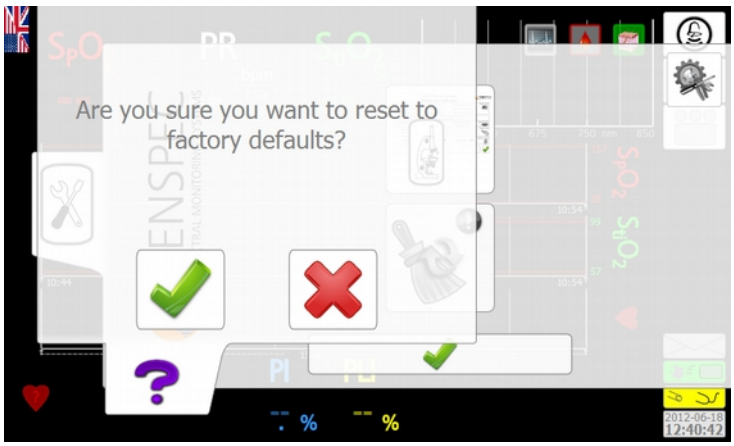
- PHILIPS IntelliBridge open interface protocol

The selected field is shown in gray.

POST and reset menu:



In this submenu, you have the option to display the POST screen (s. sec. 6.6.1 Turning on the VSM) again, or reset the settings to factory settings. Before you can actually reset the settings to factory settings, a security query is shown:

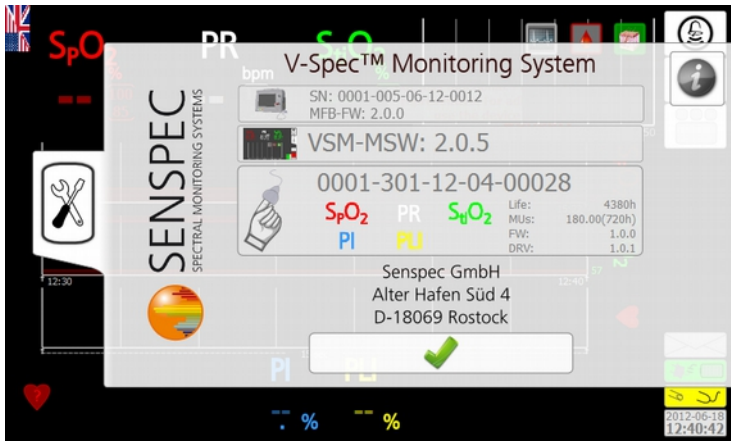


Performing the settings reset will restore following settings to the factory default values:

- alarm melodies,
- volume settings,
- display lightness,
- night mode,
- parameter alarm limits and
- parameter selection of the trend graph fields

Information in the information menu:

Via the Information menu additional information to VSMS will be made available to you:



The top row displays the serial number of the VSM and the firmware version of the multifunctional board. The second field shows the version number of the VSM monitoring software. The third and largest field shows the serial number of the connected V-Spec ™ sensor, the enabled measurement parameters, the remaining operating time, and the version numbers of the sensor firmware and of the sensor driver.

Below you will find the Senspec contact address.

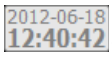
6.5.1.5 Language setting

By touching the button (9.5) in the upper left corner of the screen you can choose between the languages German and English. The currently selected language is shown in the upper left corner of the screen:

English:

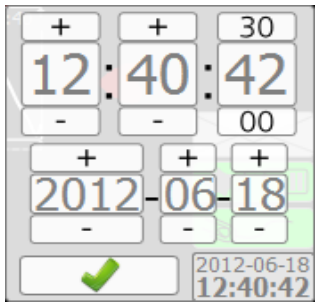
German:

6.5.1.6 Setting Date and Time

Open the sub-menu date / time by touching the symbol (7.5) 

.

The menu for setting the date and time will open up:



The date and time can be set by pressing the correspondent + or - buttons.

Confirm the entry with the "confirm" box , which closes the menu.

6.5.1.7 Storage of the user settings

Table 1 gives the default settings, and what settings made by the user are stored at a restart and which will be reset to the default values.

Table 1: Settings-Management

Setting	Default values	Setting
SpO2 Limits	85%, 100%	SpO2 Limits
PR Limits	40 bpm, 150bpm	PR Limits
StiO2 limits	60%, 95%	StiO2 limits
Alarm system status	ON	Alarm system status
Alarm volume	75%	Alarm volume
Pulse tone volume	0%	Pulse tone volume
System-click-volume	25%	System-click-volume
Melodies	OFF	Melodies
Dimmer	100%	Dimmer
Night mode	OFF (DAY)	Night mode
Time	GMT + 1h	Time
Audio-OFF-Time	30 seconds	Audio-OFF-Time
Trend views	1. SpO2, (time frame: 10min) 2. StiO2, (time frame: 10min) 3. Pleth (time frame: 12sec)	Trend views

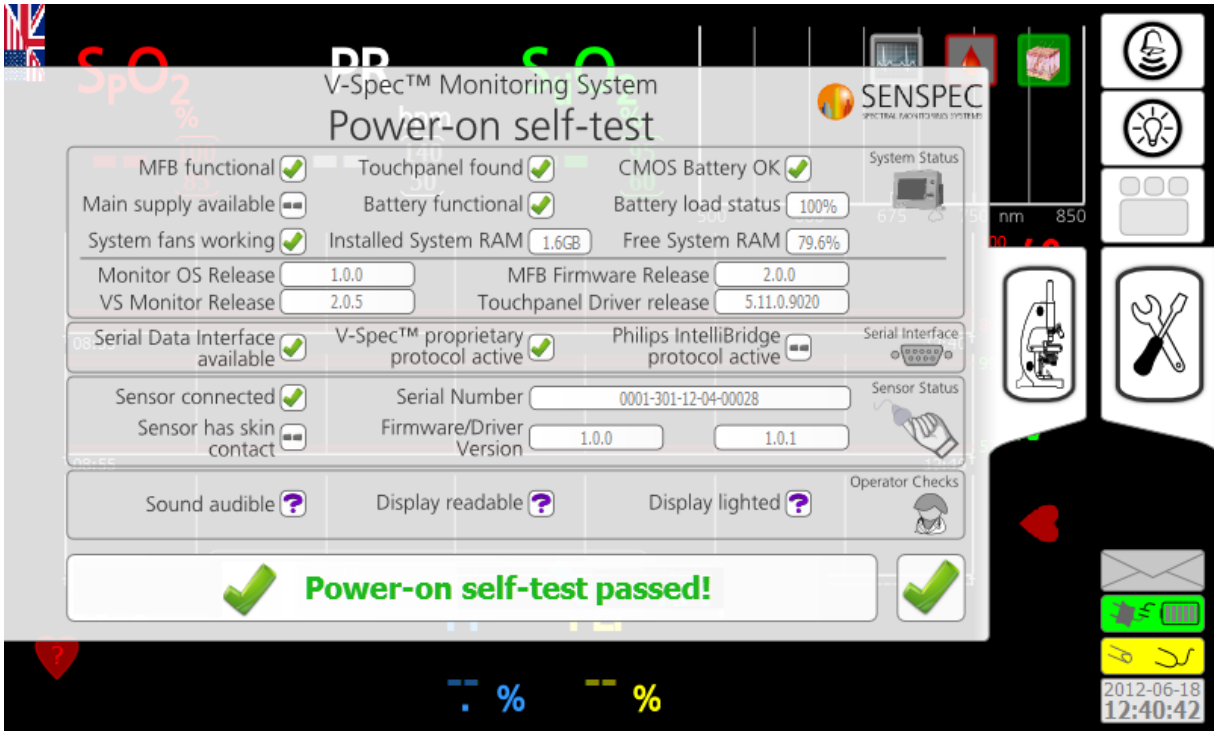
6.6 The Monitoring with the V-Spec™ Monitoring System

Connect the sensor to the V-Spec™ Monitor as described in section "Connecting a V-Spec™ Sensor". Check the sensor status by means of the sensor status indicator on the screen of the turned on VSM (7.4).

Note: The operating life of the V-Spec™ Sensors is limited. Please refer to the instruction manual of the sensor for more information!

6.6.1 Turning on the VSM

Turn on the VSM by pressing the power switch (14) n the back of the VSM. After turning on the VSM the Senspec-Logo appears. When you turn on the VSM it performs a self-test *("Power-on self-test (POST)")*. The result is displayed to you on the so-called POST-screen shown below:



On the POST screen serial number, software releases, existing interfaces, tested functions and the respective status will be displayed:

- **Green check mark:** ✔
  Test was successful,
- **Red check mark:** ✖
  could not be verified or there is a problem.

In addition to the tests that the system can automatically perform, further states are to be checked. These tests relate to the audio system and the display and are to be performed by the user. They are marked with a question mark ? . Upon starting the VSM gives an audible signal. If no signal tone is audible and/or the display is not lit or not readable, the VSMS is not functional and must not be put into operation.

If the "Power-on self-test" failed, the message "Power-on self-test not passed! (Error xxx)" appears where xxx represents an error code. In this case, the VSMS cannot be put into operation. If the test was successful, the message "Power-on self-test passed!" appears, the post-screen is automatically closed and the V-Spec™ Monitor is ready for operation.

Caution: If problems occur, immediately contact the responsible service personnel!

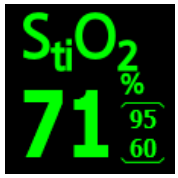
6.6.2 Medical measurement parameters

The display area "medical parameter" (2) shows you the medical variables. These are the:

- Oxygen saturation of the arterial blood S_PO_2 in %:

- Pulse rate PR in bpm:

- Oxygen saturation of the tissue $S_{ti}O_2$ in %:



In addition to the values the current alarm limits and unit of measure will be displayed.

Note: If the alarm system is muted, instead of the alarm limit the text "OFF" is displayed. This is an additional reference that the acoustic alarm system is deactivated.

6.6.2.1 Setting the alarm- limit

By touching the medical parameters, an input box opens in which you can set the alarm limits. You can do this either by a slider, or by entering a numerical value.

The slider bar has areas with different colors. Thus physiological meaningful limits are marked. If a limit value is set within the orange or red zone the color of the limit value varies according to the range.

The adjustable alarm limits and the default values are listed in Table 2. Table 3 contains the colored areas on the slider bar.

Table 2: maximum and minimum alarm limits and default values

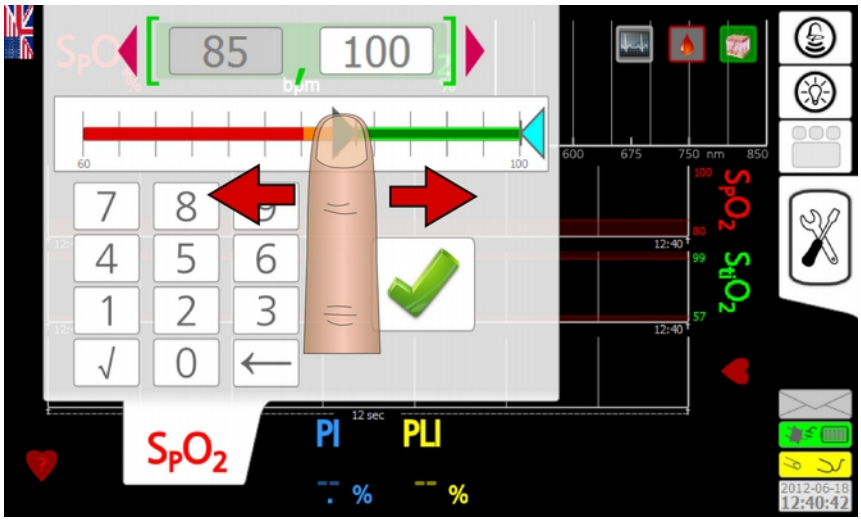
Parameter	[Minimum; Maximum]	Default Values
S_PO_2 [%]	[60;100]	[85;100]
PR [bpm]	[30;240]	[50;140]
$S_{ti}O_2$ [%]	[0;100]	[60;95]

Table 3: Physiological mark on the slider bar

Parameter	Red	Yellow	Green
S_PO_2 [%]	60-79	80-84	85-100
PR [bpm]	30-40; 200-240	40-50; 140-200	50-140
$S_{ti}O_2$ [%]	0-35	35-45	45-100

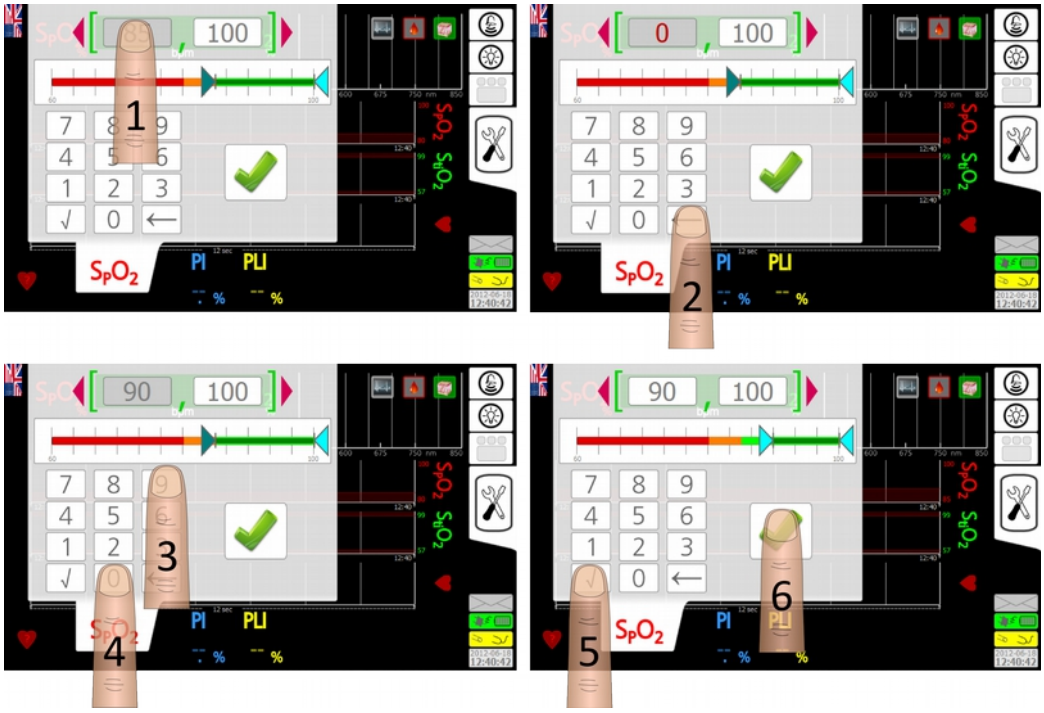
Adjusting with the help of the slider:

Press the Slider of the upper or lower limit and shift it on the desired value. The field of the selected limit will be grayed and the value will be updated immediately:



Adjusting by means of the numeric keys:

Press the limit value you want to change (1). Delete the current positions with the delete key (2). Enter the desired value (e.g. "90": 3+4) and confirm the input with the small confirmation field (5). The new limit is displayed updated. If an invalid value is entered (e.g. upper limit less than lower limit or limit outside of the adjustable range), the value will be adjusted automatically. Confirm the set limit values, by pressing the confirm button (6).



Note: Please note that not all set alarm limits are stored in a system reboot. Detailed information can be found in the section 6.5.1.7 Storage of the user settings.

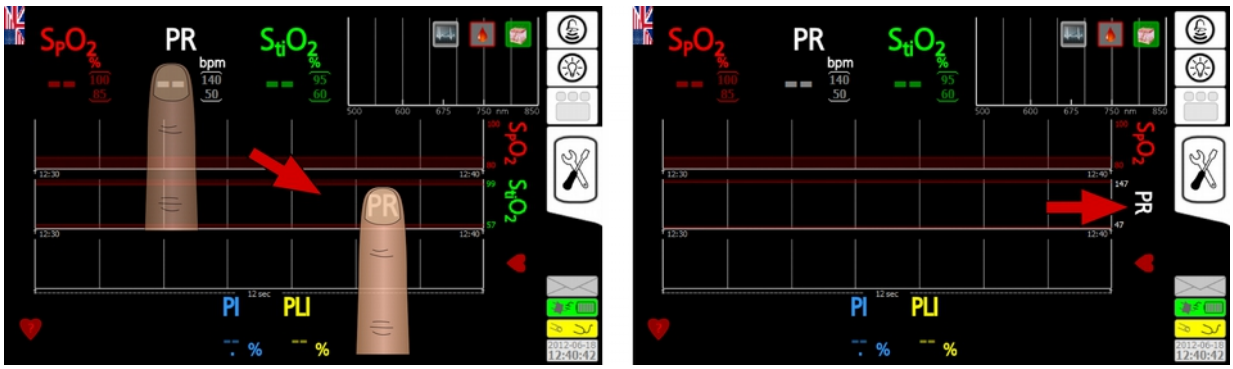
6.6.3 Display area trend graphs

Note: Align the screen display so that you, as a user, in respecting the responsibility for the patient, have the best overview of the required values for your application.

6.6.3.1 Trend graphs

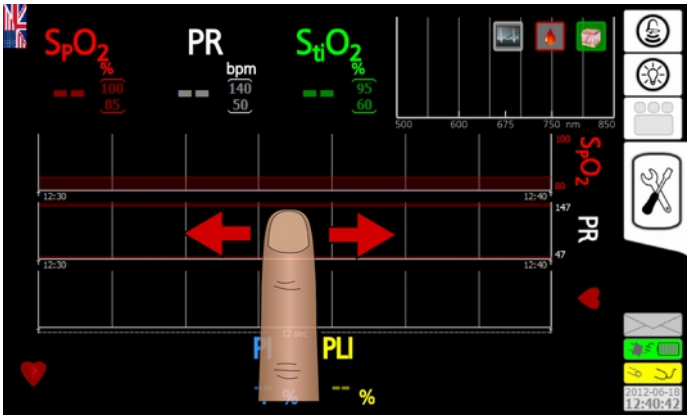
The V-Spec™ Monitor has a display area for the trend graphs (3), which you can customize. It consists of the field (3.1), (3.2) and (3.3). The trend graphs are displayed with the same color as the corresponding parameters. You can assign each field one of the medical and technical parameters, by dragging the symbols (2.1), (2.2), (2.3), (6.1) or (6.2) to the desired

field (3.1), (3.2) or (3.3):



A parameter can also be used in several fields parallel.

Below the edges of the trend graphs the time span of the trend graph can be seen, whereby the current time is shown on the right. You can change the time span by pressing on the field and wipe to the right or left:



The time span is set for all trend graphs and can be adjusted between a minimum of 10 minutes and a maximum of 72 hours. The value range of trend graphs is automatically scaled for the medical parameters, according to the values displayed in the selected time range. Maximum and minimum of the display are visible as numeric values right next to the field. The current alarm limits are shown as red horizontal lines. The area outside of the alarm limits is highlighted in red.

6.6.3.2 Plethysmogram

The plethysmogram can be displayed by dragging the heart symbol on one of fields (3.1), (3.2) or (3.3). The time span of the plethysmogram can be set equivalent to the trend graphs, and can be set to a value between 15 and 75 seconds in 15-second increments. The set time span is visible below the plethysmogram. The scaling of the height of the plethysmogram is carried out automatically for the selected range.

6.6.4 Heart symbol

The active pulse (pulse cycle) is apparent in the vibrant heart symbol (4) . f no sensor is connected or applied or the pulse rate is too low, the heart-symbol is displayed with a question mark .

6.6.5 Technical parameter display area

In the lower screen area you see the display area (6) for the technical parameter "Pulsation Index" PI (6.1) and „Pleth Index“ PLI (6.1).

6.6.6 Alarm Indicator field

The alarm indicator field (7.1) shows the alarm status in the event of an alarm.

Note: The alarms are explained in more detail in the section "Alarms and Messages”.

6.6.7 Message system

The symbol (7.2) includes the message system of the V-Spec™ Monitor. Here the latest news and information is displayed in English, to assist the user in operating the VSMS.

New messages will appear as a banner and disappear again after a few seconds. If several messages are present at the same time, the information about it takes place at the end of the message (e. g.: *Sensor is now connected but without contact to patient's skin! (1more)"*). By touching the message in the foreground it will disappear or the next message will appear.

If the symbol (7.2) is touched, already disappeared messages of the systems can be accessed again.

Note: A detailed overview of all messages can be found in section "Alarms and Messages"

6.6.8 Power status

The V-Spec™ Monitoring System is equipped with a rechargeable internal lithium ion battery to bridge a power interruption of one hour maximum without the need for measurements to be interrupted.

Caution: The battery must only be replaced by authorized qualified personnel. If you find a defect in the battery, inform your service partner immediately.

The VSM can operate on battery or on AC power. Information on the status of the power supply gives you the power status indicator (7.3), which informs you about the following states of the power supply:

Power mode active, battery fully charged:

- The VSM is connected to the external power supply and the battery is fully charged.

Power mode active, battery fully charged:

- The VSM is connected to the external power supply and the battery is charged.

Battery mode active, Battery fully charged:

- The battery is fully charged and enables the operation for approx. 1h

Battery mode active, battery charge low:

- The battery charge level decreases. The operation is possible for **max. 15 min**. A medium priority alarm informs you about it.

battery operation active, battery load critical:

- The battery load does not suffice for the operation of the VSMS. The system shuts off four minutes after the appearance of the symbol and the alarm *"Critical Battery charge"* if no power cord is connected.

A re-charging is carried out automatically when connected to the electrical network. If the battery is fully discharged, approximately four hours are required to fully charge the battery.

6.6.9 Sensor status

The status indicator of the sensor (7.4) nforms you about the current status of the sensor. This is supported by the message system. The indicator shows you the following states of the sensor:

Sensor not connected:

- There is no sensor connected to the VSM

Sensor not applied:

- The sensor is connected to the VSM, but has no skin contact to the patient.

Sensor active:

- The sensor is connected to the VSM, applied on the patient and is working properly. Following the stabilization of the readings, you can see it on the screen.

Sensor temperature is too high:

- The sensor is connected to the VSM, applied on the patient and the sensor temperature is too high. The sensor turns off, a high priority alarm is generated and the text message "High sensor temperature - remove or change sensor!" appears.

Warning: Remove a sensor with a too high temperature immediately from the patient and from the VSM! The alarm is only ended by removing the sensor from the VSM.

Caution: If a too high temperature is displayed at a sensor frequently, the sensor must not be used again! In this case, use a different V-Spec™ Sensor and contact your Senspec partner!

Sensor operating time has expired:

- The sensor is connected to the VSM and the operating time of the sensor has expired. The sensor turns off (**please note below!**), a medium priority alarm will be generated and the text message "Sensor operation period exceeded!" will be displayed.

Note: If the remaining operating time is under 60 minutes, the yellow, flashing text message "connected sensor's lifetime expires in 'xx' minutes! Please change the sensor!" is displayed on the spectra display area ⑩ ('xx' s the number of minutes remaining).

If the sensor is applied while the operating time expires, it will remain in operation and is only disabled if it is disconnected more than 15 minutes from the skin or from the VSM. In this case, the red, flashing text message "connected sensor's lifetime has expired! Please change the sensor!" will be displayed on the display area of spectra ⑩. A measurement operation can thus be maintained even with expired sensor.

6.6.10 Operation with the V-Spec™ Sensor

6.6.10.1 The measurements

If the sensor is properly connected to the patient and to the VSM after a short stabilization period the current readings of the patient will appear.

Caution: Make sure that the sensor does not move at the application site. Motion artifacts can distort the measurement. Note the course of the plethysmogram to identify motion artifacts.

Note: If the readings do not stabilize themselves, test the correct fit of the V-Spec™ Sensors. Make sure that the sensor cable is fixed to ensure a good strain relief.

Falling below the SpO_2 value triggers a high priority alarm. Be sure to verify the patient's status. A strong decrease of the SpO_2 value produces sometimes a life-threatening condition of the patient.

Falling below the $StiO_2$ value produces an alarm of medium priority. Be sure to check the status of the patient, look for any limitations in circulation. Check if, an extreme change in the physiology of the patient or in the circulation at the monitoring point has occurred (e. g. by the inflated cuff of a sphygmomanometer, a bruise, arterial blood sampling at the hand at which the sensor is located, heavy hypotension, peripheral constriction of blood vessels in response to hypothermia, drugs administered or Raynaud's syndrome).

It is possible that pulse oximeter at extremely low perfusion may only measure the peripheral saturation, which may differ significantly from the central arterial saturation. This "localized hypoxemia" may be a consequence of the metabolic demands of other tissues, extract the oxygen proximal to the monitoring location under conditions sustainable of peripheral hypo perfusion. (This can also occur in the case of a pulse rate, which correlates with the ECG heart rate.)

Caution: If frequently a weak blood circulation is displayed, a better perfusion application site must be sought. Until that is done, the oxygenation status of the patient must be checked in a different way.

Corrective Action:

f the S_PO_2 display values show significant differences the following should be done:

- Ensure that the sensor is applied correctly and safely on the patient
- Select a application site with the best possible circulation
- Rub the measuring site with 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds in order to improve the blood circulation. Strong vasodilatory creams, such as like nitroglycerin ointment, are not recommended.
- If possible, remove electro-surgical or other devices that may cause electrical interference
- If possible place the sensor at a location with low ambient light. The VSM with integrated V-Spec™ Technology is sufficiently protected against ambient light, but excessive ambient light can cause measurement errors.

Caution: If there are doubts as to the accuracy of measurements, the vital signs of the patient should be checked in any other way before the functionality of the VSM will be further investigated.

7 ALARMS AND MESSAGES

7.1 Introduction

In the following section the VSMS alarm system as well as the messages displayed on the display will be explained in more detail.

The alarm system is an important element in the VSMS. The operator should be familiar with the following information before the system is put into service.

The V-Spec™ Monitoring System allows the acoustic and visual output of alarm conditions. The acoustic alarm messages will be issued over the built-in speaker of the V-Spec™ Monitor. The visual output is carried out through various displays on the screen of the monitor. A distinction is essentially be made between the visual alarm indicators and the reporting system. The audible alarms can be muted for a period of a half minute, one minute, or two minutes, the visual alarm output can not be disabled.

Warning: Always adjust the volume of the alarm system to the ambient noise! Alarm conditions may not be observed or noticed too late if you do not follow this instruction.

7.2 Alarms

The alarms of the VSM are distinguished in "high", "medium" and "low". The alarms will be further divided into medical and technical alarms. The table 4 contains a general overview of the possible alarms.

Table 4: VSMS overview of the alarms

Alarm	Description	
High priority	• Audible and visual alarms for exceeding the S_PO_2 -limits (medical, with optional melody) • Audible and visual alarms for a critical battery level (technical, only as melody alarm) and a too high sensor temperature (technical, no melody)	Immediate response required
Medium priority	• Audible and visual alarms for exceeding the alarm limits of the parameter pulse rate, and $S_{ti}O_2$ (medical, with optional melody) • Audible and visual alarms for problems with the monitor (POST failed), the sensor (operating time has expired, not calibrated, not connected, without skin contact), the battery (defective, low battery condition (only melody alarm)), at connection problems with the multi-functional board or a defective V-Spec™ extension cable (technical, without a melody)	Immediate response required
Low priority4	• Acoustic and visual alarms at low signal quality, exceeded parameter update period or an identified problem with the monitor (technically, without a melody)	Attention and response required

7.2.1 Acoustic Alarm Indicators

The acoustic alarm tones (without melody) are marked as follows:

High priority: Sequence of ten high sounds, sounding in four bursts (3,2,3,2), repeating every 10 seconds

Medium priority: Sequence of three medium pitch tones, sounding as a single burst, repeating every 10 seconds

Low priority: Sequence of two low pitch tones, sounding as a single burst, repeating every 30 seconds

Audible alarm signals can be muted with the help of the alarm pause button 9.1 for 30 seconds, one minute or two minutes (push > 3 seconds).

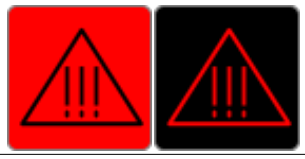
Note: The permanent muting of the alarm system is permitted only to authorized users and only available with a PIN-code. As a reminder, that the alarm system is inactive, you will hear a "reminder signal" every ten minutes.

Note: For more information on the alarms and the alarm melodies that can be optionally set parameters specific can be found in section 9.7.2 Alarm melodies

7.2.2 Visual Alarm Indicators

A distinction is made between medical and technical alarms with the visual alarms. A list of all visual alarm indicators can be found in table 5 .

Table 5: Visual alarm indicators in the VSMS

Alarm	Medical	Technical
High priority	Red frame around the S_PO_2 value, flashing with f=2Hz	Red symbol with three exclamation marks, flashing with f=2Hz 
Medium priority	Yellow frame around the value, flashing with f=1Hz	Yellow symbol with two exclamation marks, flashing with f=1Hz
Low priority	No medical alarm low priority included in the VSMS	Symbol in Cyan cyan icon with an exclamation mark, static

7.2.3 Alarm Limits

The adjustable alarm limits are listed in table 6.

Table 6: maximum and minimum alarm limits and default values

Alarm	[Minimum;Maximum]	Default Values
S_PO_2 [%]	[60;100]	[85;100]
PR [bpm]	[30;240]	[50;140]
$S_{Ti}O_2$ [%]	[0;100]	[60;95]

Note: The alarm limits of the S_PO_2 parameter are set back to the default values [85;100] each time the monitor is re-booted.

7.2.4 Alarm messages

In addition to the audible and visual alarms the VSMS issues more information and descriptions of the alarm as a text message in the English language via the message system VSMS (see section 6.6.7 Message system). You can find an overview of all alarms and the associated messages in table 7. Z In addition, the table contains information, whether an alarm melody is available optionally ("opt.").

In addition to the alarm messages also information are issued which signal no alarm. Like the alarm messages the info messages contain important information and must not be ignored. The information messages are shown in table 8 .

Table 7: Alarms in the VSMS and associated messages

Priority	Type	Alarm description	Melody	Message (English & German)
High priority	Med.	low S_PO_2 saturation	opt: S_PO_2	S_pO_2 low limit violation! S_PO_2 unterschreitet den Alarm-Grenzwert!
		high S_PO_2 saturation	opt: S_PO_2	S_pO_2 high limit violation! überschreitet den Alarm-Grenzwert!
	Tech.	Critical battery load	fix: battery-critical	Critical battery charge – connect main supply or VSM will shut down! Batterie kritisch - Netzstecker anschließen oder Abschaltung erfolgt!
		Sensor temperature too high	---	High sensor temperature – remove or change sensor! Überhöhte Sensortemperatur - Sensor entfernen oder ersetzen!
Medium priority	Med.	Low pulse rate	opt.: PR	PR low limit violation! PR unterschreitet den Alarm-Grenzwert!
		High pulse rate	opt.: PR	PR high limit violation! PR überschreitet den Alarm-Grenzwert!
		low S_PO_2 saturation	opt.: $S_{ti}O_2$	$S_{ti}O_2$ low limit violation! $S_{ti}O_2$ unterschreitet den Alarm-Grenzwert!
		High $S_{ti}O_2$ saturation	opt.: $S_{ti}O_2$	$S_{ti}O_2$ high limit violation! $S_{ti}O_2$ überschreitet den Alarm-Grenzwert!
	Tech.	Power-on self-test failed	---	Power-on self-test failed with error xx! Power-On-Self-Test fehlgeschlagen! Fehlercode: xx
		Sensor operating time has expired	---	The sensor operation period is exceeded! Sensor hat seine Lebens-/Betriebsdauer überschritten!
		Sensor not calibrated	---	The connected sensor is uncalibrated! Der angeschlossene Sensor ist nicht kalibriert!
		Sensor not connected	---	Lost connection to the sensor! Verbindung zum Sensor verloren!
		Sensor not installed	---	Sensor lost skin contact! Sensor hat den Hautontakt verloren!
		Low battery load	Fest: battery_low	Low battery charge! Der Betterieladezustand ist niedrig!
		Defective battery	---	Battery defective! Die Batterie ist defekt!
		Multi functional board not attainable	---	No connection to multifunction board! Keine Verbindung zum Multifunktionsboard!

Low priority	Tech.	Weak signal quality	---	Low signal quality! Die Signalqualität ist gering!
		Parameter update time exceeded for more than 30s	---	Data update period exceeded 30 seconds! Der letzte gemessene SpO2-Wert ist älter als 30 Sekunden!
		Monitor error	---	Monitor fault xx! Kritischer Monitor-Fehler %i!

Table 8: Information messages

Messages
Power-on self-test passed! VSM is ready for use!
Power-on self-test failed with error xx!
Sensor is now connected but without contact to patient's skin!
Low pulsation index! Please check sensor application!
Main supply disconnected!
Main supply is not connected!
Main supply connected!
Monitor problem xx!

7.2.5 Required Responses

The required responses to the alarms are provided in table 9.

Table 9: Alarms and required response

Alarm description	Required Response	Consequences, if response is lacking
S_PO_2 saturation low	Immediately, check patient status, terminate any hypoxia	Death or irreversible damages
S_PO_2 saturation high	Immediately, check patient status, terminate any hypoxia	Irreversible damages, reversible damages
Critical battery load	Immediately, connect the power cord	VSM shuts down, monitoring can not be continued
Sensor temperature too high	Immediately, remove sensor and, if required, replace by other V-	Pain and reversible damages to the measuring point by burning, sensor

	Spec™ Sensor	terminates measuring operation, monitoring can not be continued
Low pulse rate	Promptly, check patient status, terminate any bradycardia	Irreversible damages, reversible damages
High pulse rate	Promptly, check patient status, terminate any bradycardia	Irreversible damages, reversible damages
S_PO_2 saturation low	Promptly, check patient status, terminate any hypoxia/ischemia	Irreversible damages, reversible damages
S_PO_2 saturation high	Promptly, check patient status, terminate hypoxia	Irreversible damages, reversible damages
Sensor not calibrated	Promptly, replace V-Spec™ Sensor and send it to your Senspec partner	Monitoring cannot be continued
Sensor operating time has expired	Promptly, replace V-Spec™ Sensor	Monitoring cannot be continued
Sensor not connected	Promptly, connect V-Spec™ Sensor with VSM	Monitoring cannot be continued
Sensor not installed	Promptly, install V-Spec™ Sensor again at measuring point	Monitoring cannot be continued
low battery load	Promptly, connect power cord	Battery is discharged, monitoring can be continued limited
Defective battery	Promptly, contact your Senspec partner	Monitoring cannot be continued
Multi function board not attainable	Promptly, contact your Senspec partner	Monitoring cannot be continued
Sensor extension defective	Promptly, contact your Senspec partner	Monitoring cannot be continued
Weak signal quality	Timely, check Sensor application, change measuring point or stimulate blood circulation	Measured values may not match the actual parameter values
Parameter update time exceeded	Timely, check Sensor application, change measuring point	Measurement of the parameter is not possible
Monitor error	Timely, turn off VSM, contact Senspec partner	Damage to the VSM

7.3 Alarm-System-Reset

If the V-Spec™ Monitor is switched off, certain settings are reset to default value if they have been changed by the operator. This is also the case if the system is restarted after a "Critical battery load" alarm. A list of the default settings and if the standard values or user inputs are added after a reboot can be found in table 1 in chapter Fehler: Referenz nicht gefunden Fehler: Referenz nicht gefunden on page 35. If an error occurs when you save the user settings, it may happen that all settings will be set back to the default values.

7.4 Alarms in the past

The VSMS stores alarms that have occurred. This gives the user information about alarm states that lie in the past and are otherwise not directly visible.

In the case of medical alarms a past alarm is indicated by a slow flashing alarm icon next to the corresponding parameters. Past technical alarms will be signaled by a slow flashing alarm symbol in the alarm indicator field (see section 6.6.6 Alarm Indicator field). By tapping on this alarm symbol the corresponding alarm message will appear. In addition to the text of the alarm message also the time of the first occurrence of the alarm is displayed. By tapping on the message it will disappear.

7.5 Alarm triggering

From the occurrence of an event on the patient (e.g. hypoxia) to the triggering of the alarm system-related delays occur. The parameters are subject to different notification procedures that cause this delay. The "*parameter update period*" is 1Hz in the VSMS. The time that elapses until the update of the displayed parameters, i.e. the time between two valid values is therefore one second.

Figure 1 illustrated the delay that occurs from the entry of an event until triggering the alarm with an exemplary S_PO_2-course. The alarm condition occurs at time t_1 and is detected at time t_2 by the algorithm. At time t_3 the alarm is issued. The time period t_2-t_1 is

determined by the averaging and processing times of the algorithms and is called "*alarm condition delay*". The time period t_3-t_2 is the delay occurring by the signal run time within the VSMS or by the alarm forwarding to the connected systems and is called "*alarm signal generation delay*".

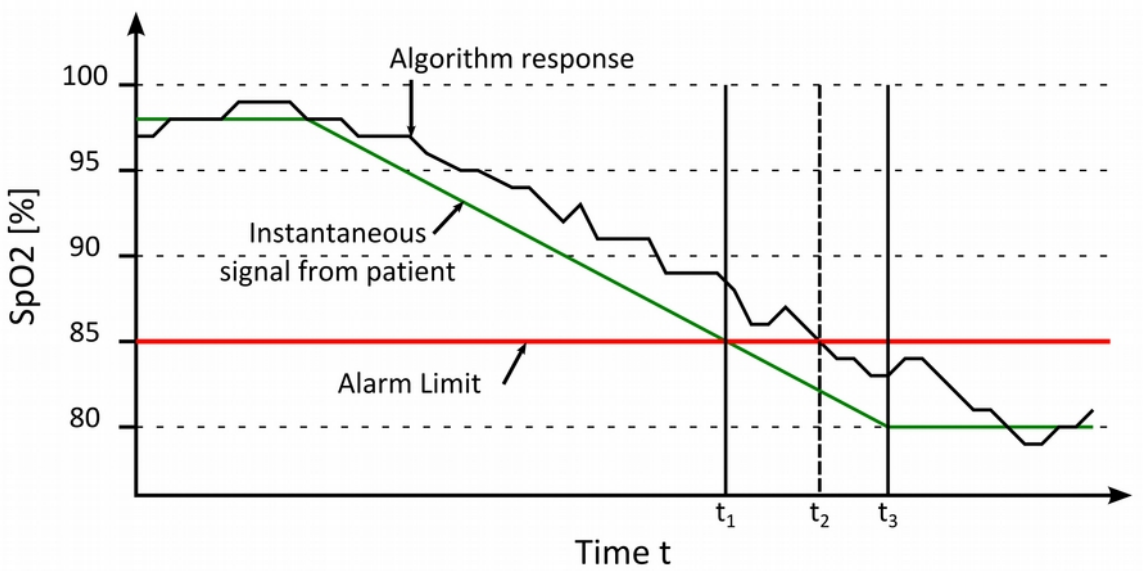


Figure 1: Illustration of the alarrm delay at the instance of parameter S_PO_2

If the VSMS is used as standalone system, the time t_3-t_2 is significantly less than one second, which is below the „parameter update period". Since the time t_3-t_2 to the time t_2-t_1 is negligible, the overall delay is mainly characterized by the time t_2-t_1.

The delay times of the medical alarms are given in table 10.

Table 10: Delay times of the alarm system

Alarm	Delay *t2-t1*
S_PO_2	15 seconds
PR	5 seconds
$S_{ti}O_2$	15 seconds
Technical alarm	<1 seconds

The delay time from determining the alarm condition (t_2) until the output over the serial port, is a maximum of two seconds.

Note: If the VSMS is used in connection with other systems, the delay times of the designated manufacturer are valid for the connected system.

Note: While a parameter is invalid or is stabilized, the alarm-monitoring of this parameter is inactive. Detailed information can be found in the section 9.2.2 .

7.6 Alarm Log

The VSM records internally the alarms in log files. At each start of the VSM a new file is created. This is permanently stored even in the case of the loss of the operating voltage. In a log file for each alarm event (start, end, limit changes ...) an entry is created, which is named with the respective alarm ID. As entries of the events are included:

- Time,
- Alarm event type (Start (START), end (END), limit change (LIM), Alarm system status (ASS)) (LIM and ASS only if there is an alarm),
- Alarm priority,
- Alarm description,
- set alarm limits,
- The current parameter value
- Alarm volume and
- Alarm system status.

Note: The alarm log file is saved internally and can be read only by authorized personnel.

8 DATA COMMUNICATION

8.1 Overview

During the V-Spec™ monitoring, current patient data can be issued via the serial interface ⑰ (RS-232), which is located on the side panel of the VSM. This port can be connected with external instruments such as multiparameter monitors, personal computer (PC) and Poly (SOMNO) graphs. When connecting the VSM to an external device, verify correct operation prior to clinical use. Both the VSM and the external device must be connected to an earthed wall socket. The respective communication protocol must be set up as described in this section.

Each PC or non-medical instrument, which is connected to the serial VSM data interface, must be certified according to the IEC 60950-Standard. All combinations of equipment must correspond to the requirements of the IEC standard 60601-1. Anyone who connects an external device with the VSM configures a medical system and is therefore responsible to ensure that the system corresponds with the requests of the standard to IEC 60601-1-1 and the electromagnetic compatibility standard IEC 60601-1-2.

Warning: If you connect devices with the V-Spec™ Monitor via the serial interface, be sure to use the RS232 isolator (ref: "RS232-IS")!

8.2 Data protocol

8.2.1 Serial data interface

The serial interface ⑰ of the V-Spec™ Monitor is used to enable a serial data communication between the V-Spec™ Monitor and other devices. The interface is located on the right-hand side of the VSM:

The layout of the interface connector is visible in the following figure:

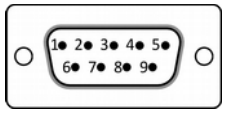


Table 11 specifies the Pin arrangement:

Table 11: RS232 pin assignment

Pin	Explanation
1	Reserve
2	Transmit Data (Tx)
3	Receive Data (Rx)
4	Reserve
5	Signal ground
6-9	Reserve

8.3 V-Spec™ Link communication protocol

The **V-Spec™ Link** communication protocol is a proprietary uni-directional protocol, to enable the exchange of real-time patient data between the V-Spec™ Monitor and other devices.

8.3.1 Interface settings

For establishing a communication the parameters at the receiver must be set according to table 12 :

Table 12: RS232-Interface settings

Parameter	Setting
Standard	RS-232
Baud rate	9600
Data bits	8
Stop bits	1
Parity	None
Flow Control	None

8.3.2 V-Spec™ Link data transfer

The V-Spec™ Link communication protocol issues one data row per second. The header will be issued every 50 seconds, or in case of a change of information contained in the header (e.g. alarm limits).

The output of the parameters is carried out delayed via the serial interface to the output on the screen. The delay is a maximum of two seconds. Not included here is the time for the processing and output to the connected device.

8.3.3 Layout of the header and the data arrays

The data output takes place in ASCII-format, whereby the fields are separated by tabs. The structure of the header and the data arrays is specified in table 13:

Table 13: Assembly V-Spec™ Link protocol

Monitor Header Info	Line 1 Line 2	Monitor-SN: <Value> *Serial number of VSM* Software: <Value> *version number of the VSM Monitoring Software*
Sensor Header Info	Line 1 Line 2	SN: <Value> *Serial Number* SW: <Value> *version number of the sensor software*
Data arrays Header	Line 1 Line 2 Line 3 Line 4 Line 5 Line 6 Line 7	Date&Time: [yyyy-mm-dd hh:mm:ss] S_PO_2 [%] <low limit>:<high limit> PR [bpm] <low limit>:<high limit> $S_{ti}O_2$ [%] <low limit>:<high limit> PI [%] PLI [%] Status
Data arrays	Line 1 Line 2 Line 3 Line 4 Line 5 Line 6 Line 7	<date><time> <S_PO_2 value><Limit violation>[a]) <unstable>[b] <PR value><Limit violation>[a] <unstable>[b] < $S_{ti}O_2$ value><Limit violation>[a] <unstable>[b] <PI value> <PLI value> <code>[c]

[a]) A plus sign („+“) behind a reading indicates the set value is above the upper alarm limit. A minus sign ("-") Indicates that the lower limit was exceeded.

[b]) A "u" behind a reading indicates that the returned value is marked as not stable.

[c]) The status codes contain further information of the VSMS. You can find a detailed list of all status codes under 8.3.4 Status Code.

Depending on the sensor status, the quality of the measured values will be given out as follows:

Table 14: Forms of output of the parameters

Sensor position, quality of the readings	Parameters
On Patient, parameter is valid	*Value*
On Patient, parameter not stable	*Value u*
On Patient, parameter is invalid	i
Not on patient	---
Sensor not connected	-/-

8.3.4 Status Code

The specified status codes in table 15 are put out through the serial interface:

Table 15: Status Codes

Meaning	Status Codes
Critical battery load	BC
Sensor temperature too high	HT
Incompatible sensor	SI
Sensor defective	SD
Sensor operating time has expired	SE
Sensor not calibrated	SNC
Sensor not connected	NoS
Sensor not installed	SO
Low battery load	BL
Defective battery	BD
Multifunctional board not attainable	nMFB
Sensor extension defective	ECD
Weak signal quality	LSQ
Parameter update time exceeded	UPE
Alarm system OFF	AO
Alarm system paused	AP
Power-on self-test failed	PF
Monitor problem xx	Pxx

9 TECHNICAL DESCRIPTION

The VSMS is a medical device according to EC Directive 93/42/EEC, certified according to the International Standards **IEC 60601-1**, **DIN EN 80601-2-61** and **EN ISO 10993-1**.*

* further relevant standards which were taken into account in the device production can be inquired at Senspec GmbH.

9.1 Environment, Transport and Storage Conditions

9.1.1 Transport / Storage Conditions

The following conditions apply to all units of the V-Spec™ Monitoring System (transport/ storage in original packaging)

Temperature: 0 - 50 °C (32 – 122°F)

Humidity: 10 – 93% (non-condensing)

For the listed devices, we recommend the following long-term storage conditions:

Temperature: 15 – 26 °C (59 - 78°F)
V-Spec™ Soft Sensor, V-Spec™ Sensor, Attachment Tape

Humidity: 40 – 60 %
Attachment Tape AT-VS

9.1.2 Operating Conditions

Temperature: 10 – 40 °C (50 – 104°F)

Humidity: 15 – 93% (non-condensing)

9.2 V-Spec™ Monitor (VSM)

9.2.1 Physical Characteristics

Weight: 2.9 kg (6.4 lbs)

Size: 23,4 cm x 28.0 cm x 12.0 cm (HxWxD)

Placement / fixation: standing, on rubber feet
VESA-Mount MIS-E (200mmx100mm, M4) for fixation at systems with VESA Standard

Lock: Kennsington Lock

Casing ingress protection: IPX1-splashproof

9.2.2 Display

Display type: 9" (23cm) colour display (800x480 pixel (WVGA) TFT), LED backlight, brightness 400cd/m², contrast ratio 600:1, large angel of vision (88° every direction at contrast ≥10:1).

Data update period:

- numerical values of SpO_2, PR, $StiO_2$ and all other physiological measuring values: 1s
- Pleth diagram: 40Hz
- Online trend graphs: 1s

Validity of parameter:

Table 16: Validity of parameter

Quality	Attributes	Description
Valid	Parameters displayed in pre-defined colours	The respective data are valid. The activated trend graphs are being updated. The alarm system for the parameter is active.
Instable	Parameters displayed in gray or darker colour	The respective data are not stable and probably do not reflect the patient's data. When one parameter is marked as instable, the activated trend graphs are being updated. The alarm monitoring for the respective parameter is active.
Invalid	'- -' replaces the parameter value	The respective data are instable and do not reflect the patient's data. When one parameter is marked as invalid, an "empty value" (NaN) is entered into the trend graph. The alarm monitoring for the respective parameter is not active.

Trend graphs:

- displayed parameters freely selectable
- time domain (x-axis) for online trends can be set between 10 min and 72 h
- values margin (y-axis) is scaled automatically depending on the value within the displayed time domain.

Plethysmogram:

- time domain (x-axis) selectable between 15, 30, 45, 60 and 75 seconds
- values margin (y-axis) is scaled automatically depending on the value within the displayed time domain

Display options:

- brightness can be adjusted during the monitoring
- switchable between day mode (continuous brightness) and night mode (brightness is automatically reduced, if no interaction is made (input, alarm))

The user is offered two selectable measurement displays:

Standard screen:

- updated medical and technical measuring values, alarm limits, online trends and/or plethysmogram and heart symbol
- minimized display of spectral data
- status messages
- status indicators for battery, sensor, alarm and wall clock time.
- settings of volume, display brightness, serial output protocol

Spectral screen:

- updated medical measuring values, alarm limits
- spectral data instead of trend graphs, technical parameters and heart symbol
- status messages
- status indicators for battery, sensor, alarm and wall clock time.
- settings of volume, display brightness, serial output protocol

9.2.3 Connections

- serial conetion RS-/EIA-232
- available protocols: - Philips IntelliBridge Open Interface
  - V-Spec™ Link

Note: The VSM does not provide the nurse call option.

9.2.4 Electrical characteristics

Internal battery:	rechargeable, sealed lithium-ion battery
Duration:	1.0 h (at 100 charging condition, new battery, 20°C)
Charging time:	4 h from 0% to100% charging condition
Power receptacle:	IEC 60320-C14 device connection
Mains voltage:	100 - 240V~ (50/60Hz)
Fuses:	2x 2A device fuses, time-lag fuse, 5 x 20mm
Power input:	max. 2 Ampere
Operating mode:	designed for continuous operation

Caution: The internal battery must be replaced by authorized staff only.

Caution: Chapter 11.2.1 Fuse change describes how to replace the fuses. Use only fuses with the specifications given in this manual. If you use other, not permitted fuses, any guarantee claim expires.

Electrical safety:

Type of protection against electric shock:	Class I (if mains operated) Class II (with internal voltage supply)
Degree of protection against electric shock:	Type BF, APPLIED PART – DEFIBRILLATION checked
Degree of protection against hazardous ingress of water:	IPX1-splashproof
Level of safety in the presence of a combustible mixture of anaesthetics and air, oxygen or nitrous oxide:	not suitable for this environment

9.2.5 Voltage supply

9.2.5.1 Mains operation

If the VSM is connected to the mains supply, the power status indicator shows the following conditions:

Mains operation active, battery fully charged:

- The VSM is connected to the external power supply and the battery is fully charged.

Mains operation active, battery is charging:

- The VSM is connected to the external power supply and the battery is charging.

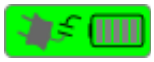
Note: If the mains operation is not displayed, while the VSM is connected to the mains, check the power cord, the socket, and the fuses.

Note: The VSM adjusts automatically to the respective local voltage (100-240V ~ (50/60Hz))

Note: Whenever the VSM is connected to the mains, the internal battery is charging. Therefore we recommend keeping the VSM connected to the mains even if it is not used. This ensures that the battery is fully charged when needed.

9.2.5.2 Battery mode

The V-Spec™ Monitoring System is equipped with a rechargeable internal lithium-ion battery to bridge a power supply interruption of one hour maximum to ensure uninterrupted measurements. If you use the VSM battery mode, the power status indicator displays the following conditions:

Battery mode active, battery fully charged: 

- The battery is fully charged and allows approximately 1h operation.

Battery mode active, battery low:

- The battery charge reduces. Operation is only possible for a max. of 15 min. A medium priority alarm indicates this.

Battery mode active, battery charge critical:

- The battery charge is not sufficient to operate the VSMS. The system switches off four minutes after the symbol and the alarm "*Critical battery charge*" were displayed.

The VSM can not be operated with a discharged battery. Therefore, connect the VSM to the mains and charge the battery for some minutes, before you switch in the VSM. The entire recharging takes about 4 hours, if the VSM is switched off.

Note: We recommend to check the internal battery every 24 months by authorized Senspec service personnel and replace it, if necessary. This must only be performed by authorized Senspec personnel. Replaced batteries must be recycled according to locale regulations and not disposed of in domestic waste.

Note: If the VSM is frequently operated in battery mode, the maximum operation time of the VSM in battery mode may decline. This may reduce the time interval between signalling the „Battery Critical" alarm and the switching off of the VSM.

9.3 V-Spec™ Sensors

The V-Spec™ Sensors are distinguished between the V-Spec™ Soft Sensor and the V-Spec™ Sensor for use of the Attachment Tape. The following characteristics relate to the V-Spec™ Sensor if not otherwise indicated.

9.3.1 V-Spec™ Soft Sensor Large

The V-Spec™ Soft Sensor is a combination of the V-Spec™ Sensor technology and the Soft-Fingerclip technology, frequently used in many standard pulsoximeters.

The sensor consists of the sensor head which contains the optical components, a shaped silicon finger clip and a cable with plug. The ergonomic shape of the silicon part which is suitable for manual cleaning ensures ease of handling and cleaning. In order to attach the sensor to the patient, slide the V-Spec™ Soft Sensor simply over the finger of the patient. The digital V-Spec™ Sensor electronic system contains information such as calibration data and Senspec identification code, which identify the sensor clearly as V-Spec™ Sensor. Any sensor without valid Senspec identification code which is connected to the VSM is not supported.

9.3.2 Physical characteristics

Sensor head:	Description:	splashprooft, reusable,
	Size:	43 mm x 16,5 mm x 24 mm (LxHxW)
	Weight:	< 8 g
	Colour:	black

Sensor cable:	Description:	highly flexible, screened PU cable
	Length:	100 cm
	Colour:	white

Note: Additional information on the V-Spec™ Sensors can be found in the special user guides for the sensors.

9.3.3 Sensor temperature

(not displayed)

Measuring range:	0 – 80°C
Resolution:	1 °C
Accuracy:	± 1 °C

9.3.4 Operating time

The operating time of the V-Spec™ Sensors is limited. Please refer to the user guides for sensors for further information.

9.3.5 Patients

The system can be used for adults and children with a body weight of more than 20 kg / 44 lbs.

9.3.6 Permissible measuring points

Table 17: Permissible measuring points

	Skin type	Patient	Measuring point
V-Spec™ Sensor (VSS) with Attachment Tape (AT-VS)	Fully developed and intact	A/P	Forehead
V-Spec™ Soft Sensor (V-SS-L)	all	A/P	Finger

Note: We recommend a flat area with good blood circulation (centrally located spots preferred). Avoid placing the sensor on top of large, superficial venues or areas with skin damages or oedema.

9.3.7 Measurement principle

Miniaturized 2D-spectroscopy system with integrated illumination unit and pulsatile time resolution for the spectral range 500nm to 850nm; for the measurement of physiological, arterial blood and tissue parameters. The measurement is performed with transflexion (remission) spectroscopy.

9.3.8 Digital microtechnology

Opto-electronic units, 2D-CMOS-Megapixel camera sensor, stabilized broad band LED illumination unit, temperature sensor, micro-controller with high-speed data transfer and storage clip located on the sensor PCB.

9.3.9 Sensor memory

Sensor data (eg spectroscopy calibration, serial number) are stored after the manufacture of the sensor. Additional data needed for the operation are stored in the sensor.

9.3.10 Sensor temperature monitoring

In order to ensure patient safety reliably, the sensor temperature is controlled by an integrated temperature sensor. If the temperature increases beyond 42°C, the sensor reduces the power of the internal power-consuming units and switches to a power save mode which does not allow normal measurement operations. The sensor returns to normal operation as soon as the sensor temperature is again within limits.

9.3.11 Sensor calibration

The V-Spec™ Sensor is checked and calibrated for its valid optical setup at the manufacturer. If the VSM does not recognize calibration data, the message „The connected Sensor is uncalibrated!" is displayed. If the sensor is properly calibrated, a re-

calibration is not required, as long as the optical setup has not been changed through external impacts. In order to ensure this, the manufacturer regularly checks and, if necessary, re-calibrates the sensors in regular intervals.

If the optical setup is impaired, the sensor is unable to recognized the blood-circulated skin (HbO2 and water spectra are recognized) and does **not** start the measurement operations.

9.3.12 Characteristics of the Sensor-LED

The illumination unit is based on a broadband fluorescent LED with a continuous spectrum in the wave length range 460nm to 880nm. The medium emitted optical output is lower than 15mW. This energy is only output if the sensor recognizes blood-circulated skin on the sensor surface. If the skin is not recognized, the sensor switches to standby mode and the medium emitted optical radiation (energy) falls below 1mW.

Note: This information is particularly important for hospitals (hospital physicians).

9.3.13 Safety

The sensor-LED light has neither angular nor spectral coherence. Therefore, the laser regulations EN 60825-1:2007 do not apply. The European legislation is based on the EU Directive 2006/25/EC (Safety requirements regarding artificial optical radiation). Special precautionary measures are not required. There are no X-ray, UV or infrared radiations.

9.3.14 Biokompatibility

The biocompatibility has been verified for the V-Spec™ Sensor and den V-Spec™ Soft Sensor in compliance with EN ISO 10993-1:2010 and the biological evaluation of medical devices, part 1. Both sensors have passed the biocompatibility test and therefore comply with EN ISO 10993-1:2010.

The sensor is free of latex. The materials used to produce the sensor do not contain raw rubber latex protein.

9.4 Attachment Tape for V-Spec™ Sensors

The material for the Attachment Tape is a product by the company 3M Health Care and the biocompatibility has been verified in compliance with EN ISO 10993-1:2010 and the biological evaluation of medical devices, part 1. Upon request, the respective clinical data sheet can be obtained at Senspec GmbH. The AT-VS is recommended for adults and children with fully developed and intact skin.

Note: Detailed information on the Attachment Tape can be referenced in the related user guide.

9.5 System Performance

9.5.1 Arterial oxygen saturation (S_PO_2; arterial)

Measurement range: 60 – 100%

Resolution: 1%

S_PO_2 accuracy in the range between 60 bis 100%:

Sensor Type	Measuring points	Accuracy Arms
V-Spec™ Soft Sensor (V-SS-L)	Finger	2%
V-Spec™ Sensor (VSS) with Attachment Tape (AT-VS)	Forehead	2%

Warning: The VSMS measures the functional oxygen saturation.

Note: The S_PO_2 accuracy specification is based on controlled hypoxy studies in healthy, adult subjects above the indicated saturation range by applying a sensor of the specified sensor type at each of the defined measuring points. The S_PO_2 measurements were compared with SaO_2 values, which were determined by analysing arterial blood. The S_PO_2 accuracy is indicated as RMS (root-mean-square).

9.5.2 Pulse rate (PR)

Measurement range: 30 – 250 bpm (beats per minute)

Resolution: 1 bpm

Accuracy: ± 3 bpm

9.5.3 Tissue oxygen saturation ($S_{ti}O_2$; tissue)

Measurement range: 10 – 100%

Resolution: 1%

Accuracy: (30 to 90%)

Sensor Type	Measuring points	Accuracy Arms
V-Spec™ Soft Sensor (V-SS-L)	Finger	3%
V-Spec™ Sensor (VSS) with Attachment Tape (AT-VS)	Forehead	3%

Warning: The VSMS measures the functional oxygen saturation in the tissue. The tissue parameters are continuous measurements via the optical path.

Note: The $S_{ti}O_2$ accuracy is based on the comparison with in vitro measurements by means of a blood gas analyser.

9.5.4 Pulsation Index (PI)

Measurement range: 0.1 – 20%

lower signal level: 0.5%

Resolution: 0.1%

9.5.5 Pleth Index (PLI)

Measurement range: 0 – 80%;

Resolution: 1 %

9.5.6 Validation

The described medical and technical parameters have been validated in comprehensive studies. In all cases, the validation was performed with all possible components of the VSMS (cf. chapter 6.1 Components and delivery). A list of validation studies can be inquired at Senspec.

9.6 System reliability

The VSM performs several tests indepenently in order to ensure the system reliability:

Power-On Self-Test	After turning on, the VSM performs a Power-On Self-Test (POST) which checks the circuits and functions (internal test).
Watch-Dog Timer	The firmware of the VSM and the V-Spec™ Sensor have a Watchdog-Timer, which resets the VSM and the V-Spec™ Sensor in the case of software errors.
Various tests which ensure the reliability of calibration.	In order to ensure the continuing reliability of the calibration of the V-Spec™ Sensor, the VSM tests automatically the camera module and the spectrometer setup.
Test of the functionality of the connected sensor	Various tests to identify potential problems or errors of the connected system are independently performed by the VSM.

9.6.1 Power-on self-test (POST)

While the VSM is booting, a Power-on self-test (POST) is performed. It includes the following inquiries:

- Multifunctional board (MFB) operable,
- Touch panel recognized
- CMOS battery functioning,
- Mains connection established,
- Battery functional,

- Battery charging condition,
- Fan functional,
- Installed RAM storage (in GByte),
- Free RAM storage (in %),
- Monitor OS Release Number,
- MFB Firmware-Version,
- VSM Monitoring Software-Version,
- Touchpanel driver version,
- Serial interface available,
- Active serial output protocol,
- Sensor connected,
- Sensor serial number,
- Sensor has skin contact,
- Sensor-Firmware-Version,
- Sensor driver version.

Apart from automatic inquiries, the operator must test the audible and visual output interfaces.

If the POST does not identify errors, the message 'power-on self-test successfully passed' is displayed for 5 seconds and the VSM changes to one of the available measurement screens. Check the date /wall clock time settings of the VSM after the POST and set them properly, if necessary.

9.6.1.1 Internal battery for the wall clock time

The VSM contains one additional internal battery, which stores the set clock time. If the voltage of the internal clock battery of the VSM falls below a critical value, the real time clock deletes the date and time settings. After restarting the VSM, date and time are set to „2008-01-01 00:00:00".

If the clock was reset due to the empty and defective CMOS battery, the POST is not passed and the VSM must not be operated.

9.6.1.2 Loudspeaker test

When booting the VSM, the „power-on self-test“ is performed, which also tests the audio system by giving three short sounds with increasing sound level.

Warning: The audible POST signals serve as acoustic confirmation that the VSM audio system is properly functioning. Do not use the VSM if you have not heard the audible signals. The audio system including the alarm system may be defective. In such cases, contact qualified technical staff or your local Senspec representative.

Warning: Check whether the alarm volume is set in a way that the operator is able to hear the alarm signals in the designed environment.

Warning: Make sure that the loudspeakers are not blocked. Otherwise an alarm could be ignored which prevents an adequate response to the alarm.

9.6.1.3 Display Test

Check whether the VSM display is readable and legible when starting the POST screen. Check the display for pixel flaws while starting the VSM.

WARNING: Do not use the VSM, if the display of the VSM is not activated or the POST identifies an internal problem (message displayed „not passed“ with respective error code on the POST screen). In such cases, contact qualified technical personnel or your local Senspec representative.

Note: The software version numbers used in the VSM are displayed on the POST screen. The software version numbers are required to get support from qualified technical personnel or your local Senspec representative. Note down the software version numbers and keep them ready when you request technical support.

9.7 Alarms and messages

The VSM has an alarm system which is described in chapter 7 Alarms and Messages. Below, further technical details on the alarms are listed.

9.7.1 Alarm volume

Depending on the priority, the alarms sound at different levels. Table 18 gives an overview of the alarm volumes (measured in front of the device with 1m distance).

Table 18: Alarm volumes

Alarm	Minimum volume	Maximum volume
High priority	62,7dBA	78,0dBA
Medium priority	58,3dBA	72,1dBA
Low priority	49,4dBA	61,9dBA

Table 19 shows the alarm timing.

Table 19: Alarm-Timing

Alarm	Item	Result
High priority	Pulse length	0,115s
	Time between 1. and 2. sound	0,06s
	Time between 2. and 3. Sound	0,06s
	Time between 3. and 4. Sound	0,25s
	Time between 4. and 5. Sound	0,06s
	Time between 5. and 6. Sound	0,5s
	Time between 6. and 7. Sound	0,06s
	Time between 7. and 8. Sound	0,06s
	Time between 8. and 9. Sound	0,25
	Time between 9. and 10. Sound	0,06s
	Interburst Interval	10s
	Rising / falling sound time	8ms
	Frequency	858Hz

Medium priority	Pulse length	0,17s
	Time between 1. and 2. Sound	0,14s
	Time between 2. and 3. Sound	0,14s
	Interburst Interval	10s
	Rising / falling sound time	12,4ms
	Frequency	487Hz
Low priority	Pulse length	0,23s
	Time between 1. and 2. Sound	0,22s
	Time between 2. and 3. Sound	0,22s
	Interburst Interval	30s
	Rising / falling sound time	15ms
	Frequency	391Hz

9.7.2 Alarm melodies

As an option, you may choose between several alarm melodies for the medical parameters. The frequencies of the alarm melodies are listed in table 20.

Table 20: Frequencies of alarm melodies

Alarm	Item	Frequency
S_PO_2-melody	Sound 1	788Hz
	Sound 2	702Hz
	Sound 3	661Hz
	Sound 4	585Hz
	Sound 5	513Hz
PR-melody	Sound 1	788Hz
	Sound 2	702Hz
	Sound 3	661Hz
StiO2-melody	Sound 1	398Hz
	Sound 2	494Hz
	Sound 3	585Hz

Note: The VSM does not interfere the audible signals, i.e. there is only one acoustic signal at a time. The VSM counts the output priority for acoustic signals as follows (sorted in descending order):

- High priority alarm
- Medium priority alarm
- Low priority alarm
- Information signals (AUDIO OFF reminder, „Power-On Self-Test" signal)
- Pulse tone
- Key sound

Note: An acoustic signal with high priority is never interrupted by a signal with low priority.

Note: Alarm signals are always completely transmitted before the system is automatically shut down (e.g. in case of low battery charge).

10 TROUBLESHOOTING

This chapter describes problems, potential causes and recommended troubleshooting the operator can initiate to fix problems. If the recommended troubleshooting did not eliminate the failure, please contact skilled Senspec service personnel.

Each problem is allocated a number PXXXX. If the troubelshooting and/ or repair requires to send the system (or individual system parts) to qualified Senspec service personnel, please always state the error number PXXX on the attached repair note. (repair form RMA), The error number facilitates the further troubleshooting process for the service personnel and reduces repair time.

Note: The PDF version of the repair note (repair form RMA) is included in the manual CD for the VSM.

The troubleshooting is classified as follows:

- Troubleshooting for the monitoring
- Sensor-specific troubleshooting
- Monitor-specific (VSM) troubleshooting

10.1 Troubleshooting for the monitor

Note: This chapter is applicable for the V-Spec™ Sensor and V-Spec™ Soft Sensor.

Problem	Potential causes	Recommended action
P0100 S_PO_2, PR and/or $S_{ti}O_2$ too low or to high	Blocked veins (e.g. in Trendelenburg position)	Procedure limited
	Cardiac arrhythmia	Prcedure limited
	Insufficient local blood circulation at measuring point	Check patient status! Shock, low cardiac index, insufficient local vasodilation restrict the procedure. Check sensor application and suitability of measuring point. Avoid potential mechanical pressure at the sensor or at the measuring point and do not pull it. Secure the sensor cable with adhesive tape and clothing clip. Remove any blood pressure cuffs, belts or similar items which may impair the blodd circulation.
	Electroacoustics, electrosurgery, defibrallation	Values get back to normal following an electroacoustics treatment, electrosurgery or defibrillation.
	Sensor is attached at a measuring point which is either not suitable or not recommended for the monitoring	The VSMS monitoring is only permitted in adults and children with over 20 kg body weight. The monitoring is only permitted for the measuring points: • V-Spec™ Soft Sensor (VS-SS-L): finger • V-Spec™ Sensor (VSS): forehead
	Artifacts/measuring errors caused by movements of the patient	Check sensor application and suitability of measuring point! Secure the sensor cable with adhesive tape or clothing clip!
	Measurements are impaired by bright ambient light	Screen the V-Spec™ Sensor against bright ambient light (e.g. lamps, sun light etc.)!
	Dyshaemoglobins	Physiological limitation of the procedure. Patients with high carboxyhaemoglobin values (e.g. smokers) the functional saturation measured with a pulse oximeter will be higher than the functional saturation values measured with an CO-oximeter.
	Intravascular dyes	Procedure limited. Dyes used as tracers, contrast agents etc, can absorb light of the same wave lenghts as the measurements use.

10.2 Sensor-specific troubleshooting

Problem	mögliche Ursachen	Empfohlene Handlungen
P0200 Although the V-Spec™ Sensor is connected to the VSM, the VSM indicates sensor not connected.	Poor contact (cable possibly not connected, contaminated contacts)	Check connections by disconnecting and reconnecting the sensor cable and/or sensor extension. Turn the device off and turn it on after briefly waiting.
	V-Spec™ Sensor	In order to identify the defective part, replace sensor and/or sensor cable extension and try again. If necessary, change the VSM position and try another VSM. If V-Spec™ Sensor is damaged, replace it by a new, original V-Spec™ Sensor.
	VSM defective	If the problem persists, contact authorized service personnel.
P0201 Although the V-Spec™ Sensor is applied to the patient, the VSM indicates sensor not connected.	Sensor lost skin contact	Check sensor application and renew if necessary.
	Sensor defective	Replace the V-Spec™ Sensor
P0202 Sensor gets too warm and causes pain.	Insufficient local blood circulation at measuring point	Remove the sensor. Re-apply only, if the cause was eliminated. Avoid potential mechanical pressure at the sensor or at the measuring point and do not pull it. Secure the sensor cable with adhesive tape and clothing clip. Remove any blood pressure cuffs, belts or similar items which may impair the blood circulation!
	Sensor defective	Remove the sensor and replace it against another V-Spec™ Sensor.

10.3 VSM specific troubleshooting

Problem	Potential causes	Recommended action
P0300 VSM does not work	VSM turned off	Turn on the VSM.
	VSM not connected to the mains and battery is discharged	Connect the VSM with the mains connection, which starts the battery charging.
	power cord defective	Select another power cord to connect the VSM.
	Fuse defective	Change fuse as described in chapter 11.2.1 Fuse change

Problem	Potential causes	Recommended action
	VSM defective	Turn off the VSM and then turn it on again. If the problem persists, contact authorized service personnel.
P0301 Display is black (off)	VSM turned off	Turn on the VSM. f the problem persists, contact authorized service personnel.
	Display / VSM defective	Contact authorized service personnel!
P0302 Display is not legible (dark)	Brightness not properly set	Set the brightness of the display as described in chapter 6.5.1.2 Brightness of the screen / night mode
	VSM defective	Turn off the VSM and then turn it on again. If the problem persists, contact authorized service personnel.
P0303 Batteriy is not charging	power cord not connected /defective	Select another power cord to connect the VSM.
	Battery defective	Contact authorized service personnel.
	VSM defective	Contact authorized service personnel.
P0304 Fully charged battery is discharged after less than 30min	Battery defective	Contact authorized service personnel.
P0305 POST Screen not hidden	Power-on self-test failed	Note the error number/message. Turn off the VSM and then on. If the problem persists, contact authorized service personnel.
P0306 VSM does not respond if touch screen is touched	VSM defective	Contact authorized service personnel.
P0307 Fan is very noisy	Fan defective or contaminated	Contact authorized service personnel.
P0308 Fan is blocked	Fan defective or contaminated	Contact authorized service personnel.
P0309 No sound	Audio output paused or turned off	Activate audio output (if necessary).
	Audio system defective	Contact authorized service personnel.
P0310 Mains connection cable cannot be connected with VSM	power cord defective	Replace power cord.
	Power connector faulty	Contact authorized service personnel.
P0311 No communication via RS-232 interface	Wrong interface settings selected at the connected device	Read interface settings in chapter 8.3.1 Interface settings and adjust settings at the connected device respectively.
	VSM defective	Contact authorized service personnel.

11 MAINTENANCE

Under normal use, the VSMS is a maintenance-free system and a recalibration or internal resetting is not required. However, in order to ensure the warranted performance, reliability and safety, you should perform regular routine checks, regular care (incl. cleaning and disinfection) and safety tests.

Cleaning and/or disinfection instructions for the VSM and the V-Spec™ Sensors including cable can be found in the respective instructions for use. We recommend manual cleaning. The system must not be autoclaved, irradiated or steam sterilized.

11.1 Routine tests

This chapter describes routine checks and maintenance work, which can be performed by the VSMS operator. Routine checks and maintenance work should be performed regularly.

Caution: Technical safety checks must only be performed by authorized service personnel in regular intervals (at least every 24 months) or in compliance with the local and statutory regulations.

The following checks should be performed regularly:

- Power-on self-test: This test is automatically performed at every restart and can be performed manually with the POST and reset menu (s. sec. 6.5.1.4 Main menu) . If you leave the VSM continuously turned on, Turn off the VSM and on at least once per month to check the Power-on self-test function.
- Check the VSM monthly for mechanical and functional damages.
- PCheck the V-Spec™ Sensors including cable for mechanical and functional damages once per month.
- Check the power cord for mechanical and functional damages once per month. Defective cables must be replaced by original spare parts.

- Check the alarm functions monthly: For this, change the alarm limits of the medical parameters in order to trigger the different alarms.
- Check occasionally the labels and markings at the monitor, sensor and all accessories for integrity and readibility. If they are damaged or not readable, address this to your authorized service technician.

11.2 Service

We recommend to perform safety tests in regular intervals (at least every 24 months) or in compliance with local and statutory regulations (for more details, refer to the Service Manual). Please contact sufficiently trained staff or your local Senspec partner to perform safety tests or repairs. Please make sure that any service or repair that requires to open the casing must only be performed by authorized Senspec service personnel.

Warning: The casing must only be opened by service personnel authorized by Senspec. There are no replacement parts for users inside the device.

11.2.1 Fuse change

The VSM has two interchangeable microfuses which are located in the fuse box (12) aat the rear of the VSM. The specification of the required fuses can be referenced in chapter 9.2.4 Electrical characteristics.

Please follow the steps below to change fuses:

1. Release the fuse socket with a small screw driver or another suitable item by slightly pressing the socket right and left:

Now the fuse socket releases from the mounting and slightly juts out the casing:

2. Remove the fuse socket:

3. Now you can either check or replace the fuse, if necessary.

4. Once you have checked or replaced the fuses, re-insert the fuse box in the same manner. Make sure that the slot in the casing matches the shape of the counterpiece at the fuse socket. Press the fuse box in the casing until it engages noticeably on both sides:

The fuse socket must be flush mounted in the casing:

11.3 Cleaning and disinfection

Warning:Turn off the VSM and disconnect it from the mains before you start cleaning the monitor.

Due to the nature and severity of infectious diseases, such as AIDS and hepatitis B, it is essential that devices and accessories which may come in contact with human and animal tissues or fluids (particularly blood), should always be considered as contaminated or potentially hazardous.

Contaminated devices and accessories must be decontaminated as described in the process below. Decontamination must be performed by a skilled person only. The instructions on cleaning and disinfection vary from hospital to hospital. If you may have any doubts or questions regarding contamination or decontamination issues, please contact your local infection authority /regulatory authority/ or hygiene department.

If devices or accessories must be returned to the supplier or manufacturer for the purpose of servicing/repairing, the operator in the clinic must ensure proper decontamination. A

„Certificate of Disinfection“ should be issued by the person responsible for the device and must be included in the return consignment for servicing and repair. If devices are serviced on site, the service technician also requires a „Certificate of Disinfection“ which must be submitted to him.

Note: A PDF template of the „Certificate of Disinfection“ is available on the manual CD for the VSMS.

Caution: Plugs and couplings must be carefully cleaned and kept dry at all times. Do not expose the VSM to humidity and do not spill liduids over or into the VSM. If the VSM got accidently wet, it must be wiped dry carefully. Make sure that the device is completely dry before you start using it.

Caution: Do not use other cleaning or disinfection methods /agents than recommended here.

Caution: Do not use solutions based on paraffin and mineral oil or acetone-based solutions or any other aggressive solvents to clean the screen. These substances can attack the device and cause a device failure.

Caution: The device and its accessories must not be sterilized by means of irradiation, steam or ethylene oxid! Autoclaving and pressure sterilization is not permitted.

Caution: Do not touch or rub the VSM surface, do not expose to cleaning powders, tools, brushes and materials with rough surfaces. They can scratch the surfaces of the VSM and the touch-sensitive screen may be damaged.

11.3.1 Recommended cleaning and disinfection methods

Use only manual cleaning methods. The devices must not be cleaned by means of autoclaving, irradiation or steam sterilization.

11.3.1.1 Basic principle

Make sure that the accessories were separated from the monitor before you start cleaning or disinfecting and that the monitor is disconnected from the mains.

Make sure that only sufficiently specified and validated procedures of the Equipment and Product Safety Act are used for the cleaning and disinfection. Regular reviews must be made to ensure that validated parameters have been used in every cycle. Observe the statutory provisions applicable in your country and the hygiene regulations in your institution. This applies in particular to the various guidelines in terms of the inactivation of prions.

11.3.1.2 Pretreatment

Remove coarse contamination directly after every treatment (within 2h maximum). For this, use water or a disinfectant-soaked cloth.

The disinfectant must be aldehyde-free (otherwise blood contamination could dry or manifest) and must have an approved efficiency classification (e.g. VAH / DGHM-or FDA / EPA- approval / clearance / registration or CE-label).

Use only a soft brush or clean, soft cloth for the manual cleaning. Under no circumstances use metal brushes or steel wool.

Please note that the disinfectant used in pretreatment is only intended for your personal safety and cannot replace the disinfection steps of the further cleaning.

11.3.1.3 Manual cleaning and disinfection

Please note the following when selecting cleaning and disinfection agents:

- General suitability for the cleaning and disinfection of plastic equipment
- Use disinfectants with proven efficiency (e.g. DGHM / DGHM or FDA / EPA approval / clearance / registration or CE label)

- Compatibility with used cleaning agents

Do not use combined cleaning and disinfection agents.

Cleaning /disinfection methods of the VSM

The monitor must only be wiped off with a disinfectant-soaked cloth. If the monitor has coarse contamination or residuals which can not be removed, hand over the device for thorough cleaning to your authorized service technician.

Caution: The monitor must not be immersed in liquid or cleaned by means of autoclaving, radiation or steam sterilization.

Cleaning /disinfection methods of sensors

Follow the respective operating instructions to clean and disinfect sensors.

11.3.1.4 Check

Check all system parts (monitor, sensors...) after cleaning and/or cleaning /disinfection for corrosion, damaged surfaces and contamination. Damaged parts of the system must not be further used. If the parts are still contaminated, repeat the cleaning /disinfection process.

If the parts should still have coarse contamination or residuals which can not be removed, hand over the device for thorough cleaning to your authorized service technician.

Warning: Under no circumstances,use contaminated parts for any monitoring process.

11.4 Shipment instructions for the VSMS

Please contact your local Senspec dealer before you return the system for safety tests and/or servicing / repair to the supplier or manufacturer.

If not covered by the warranty, the shipping costs and repair and maintenance costs are

charged to the sender.

The following instructions apply to all shipments of VSMS or parts thereof to qualified /Senspec authorized technical personnel or your local Senspec dealer:

1. If not otherwise instructed, please send the VSM with power cord and/or V-Spec™ Sensor, but without accessories.

2. Appliances must be properly disinfected! Disinfection information can be referenced in this manual or in the user guide of the sensor.

3. The „Certificate of Disinfection“ and the „Repair Form“, if applicable, must be attached to the device when shipped for a safety check and/or servicing /repair. If the devices are maintained on site, the service technician also requires a „Certificate of Disinfection“.

Note: PDF templates of the „Certificate of Disinfection“ and the „Repair Form“ are available on the manual CD for the VSMS.

4. If you wish to return electronic parts, make sure to comply with the ESD precautionary measures.

5. For any return, use the VSM original packaging, if possible or alternatively, a packaging that provides similar protection. Use only clean and hygienically perfect packaging material for your return shipment.